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Presidential Documents

Title 3—

The President

Notice of May 8, 2019

Continuation of the National Emergency With Respect to the Actions of the Government of Syria

On May 11, 2004, pursuant to his authority under the International Emergency Economic Powers Act, 50 U.S.C. 1701–1706, and the Syria Accountability and Lebanese Sovereignty Restoration Act of 2003, Public Law 108–175, the President issued Executive Order 13338, in which he declared a national emergency with respect to the actions of the Government of Syria. To deal with this national emergency, Executive Order 13338 authorized the blocking of property of certain persons and prohibited the exportation or reexportation of certain goods to Syria. The national emergency was modified in scope and relied upon for additional steps taken in Executive Order 13399 of April 25, 2006, Executive Order 13460 of February 13, 2008, Executive Order 13572 of April 29, 2011, Executive Order 13573 of May 18, 2011, Executive Order 13582 of August 17, 2011, Executive Order 13606 of April 22, 2012, and Executive Order 13608 of May 1, 2012.

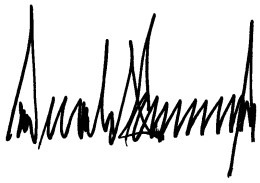
The President took these actions to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the actions of the Government of Syria in supporting terrorism, maintaining its then-existing occupation of Lebanon, pursuing weapons of mass destruction and missile programs, and undermining United States and international efforts with respect to the stabilization and reconstruction of Iraq.

The regime's brutality and repression of the Syrian people, who have been calling for freedom and a representative government, not only endangers the Syrian people themselves, but also generates instability throughout the region. The Syrian regime's actions and policies, including with respect to chemical weapons, supporting terrorist organizations, and obstructing the Lebanese government's ability to function effectively, continue to foster the rise of extremism and sectarianism and pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. As a result, the national emergency declared on May 11, 2004, and the measures to deal with that emergency adopted on that date in Executive Order 13338; on April 25, 2006, in Executive Order 13399; on February 13, 2008, in Executive Order 13460; on April 29, 2011, in Executive Order 13572; on May 18, 2011, in Executive Order 13573; on August 17, 2011, in Executive Order 13582; on April 22, 2012, in Executive Order 13606; and on May 1, 2012, in Executive Order 13608, must continue in effect beyond May 11, 2019. Therefore, in accordance with section 202(d) of the National Emergencies Act, 50 U.S.C. 1622(d), I am continuing for 1 year the national emergency declared with respect to the actions of the Government of Syria.

In addition, the United States condemns the Assad regime's use of brutal violence and human rights abuses and calls on the Assad regime to stop its violence against the Syrian people, uphold existing ceasefires, enable the delivery of humanitarian assistance, and allow a political transition in Syria that will forge a credible path to a future of greater freedom, democracy, opportunity, and justice.

The United States will consider changes in the composition, policies, and actions of the Government of Syria in determining whether to continue or terminate this national emergency in the future.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
May 8, 2019.

[FR Doc. 2019–09814
Filed 5–9–19; 8:45 am]
Billing code 3295–F9–P

Presidential Documents

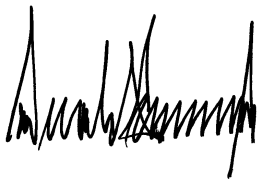
Notice of May 8, 2019

Continuation of the National Emergency With Respect to the Central African Republic

On May 12, 2014, by Executive Order 13667, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the situation in and in relation to the Central African Republic, which has been marked by a breakdown of law and order, intersectarian tension, widespread violence and atrocities, and the pervasive, often forced recruitment and use of child soldiers, threatens the peace, security, or stability of the Central African Republic and neighboring states.

The situation in and in relation to the Central African Republic continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on May 12, 2014, to deal with that threat must continue in effect beyond May 12, 2019. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13667.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
May 8, 2019.

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Rules and Regulations

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FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Docket No. R–1663; RIN 7100–AF 50]

Regulation D: Reserve Requirements of Depository Institutions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (''Board'') is amending Regulation D (Reserve Requirements of Depository Institutions) to revise the rate of interest paid on balances maintained to satisfy reserve balance requirements (''IORR'') and the rate of interest paid on excess balances (''IOER'') maintained at Federal Reserve Banks by or on behalf of eligible institutions. The final amendments specify that IORR is 2.35 percent and IOER is 2.35 percent, a 0.05 percentage point decrease from their prior levels. The amendments are intended to enhance the role of such rates of interest in maintaining the Federal funds rate into the target range established by the Federal Open Market Committee (''FOMC'' or ''Committee'').

DATES: *Effective date:* This rule is effective May 10, 2019.

Applicability date: The IORR and IOER rate changes were applicable on May 2, 2019.

FOR FURTHER INFORMATION CONTACT: Clinton Chen, Senior Attorney (202–452–3952), or Sophia Allison, Senior Special Counsel (202–452–3565), Legal Division, or Kristen Payne, Senior Financial Institution & Policy Analyst (202–452–2872), or Laura Lipscomb, Assistant Director (202–912–7964), Division of Monetary Affairs; for users of Telecommunications Device for the Deaf (TDD) only, contact 202–263–4869; Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

For monetary policy purposes, section 19 of the Federal Reserve Act (''the Act'') imposes reserve requirements on certain types of deposits and other liabilities of depository institutions.[1] Regulation D, which implements section 19 of the Act, requires that a depository institution meet reserve requirements by holding cash in its vault, or if vault cash is insufficient, by maintaining a balance in an account at a Federal Reserve Bank (''Reserve Bank'').[2] Section 19 also provides that balances maintained by or on behalf of certain institutions in an account at a Reserve Bank may receive earnings to be paid by the Reserve Bank at least once each quarter, at a rate or rates not to exceed the general level of short-term interest rates.[3] Institutions that are eligible to receive earnings on their balances held at Reserve Banks (''eligible institutions'') include depository institutions and certain other institutions.[4] Section 19 also provides that the Board may prescribe regulations concerning the payment of earnings on balances at a Reserve Bank.[5] Prior to these amendments, Regulation D specified a rate of 2.40 percent for both IORR and IOER.[6]

II. Amendments to IORR and IOER

The Board is amending § 204.10(b)(5) of Regulation D to specify that IORR is 2.35 percent and IOER is 2.35 percent, a 0.05 percentage point decrease in each rate. The Board announced this decision on May 1, 2019, with an effective date of May 2, 2019, in the Federal Reserve Implementation Note that accompanied the FOMC's statement on May 1, 2019. The FOMC statement stated that the Committee decided to maintain the target range for the federal funds rate at 2–1/4 to 2–1/2 percent.

The Federal Reserve Implementation Note stated:

The Board of Governors of the Federal Reserve System voted unanimously to set the interest rate paid on required and excess reserve balances at 2.35 percent, effective May 2, 2019. Setting the interest rate paid on required and excess reserve balances 15 basis points below the top of the target range for the federal funds rate is intended to foster trading in the federal funds market at rates well within the FOMC's target range.

As a result, the Board is amending section 204.10(b)(5) of Regulation D to change IORR to 2.35 percent and IOER to 2.35 percent.

III. Administrative Procedure Act

In general, the Administrative Procedure Act (''APA'')[7] imposes three principal requirements when an agency promulgates legislative rules (rules made pursuant to congressionally delegated authority): (1) Publication with adequate notice of a proposed rule; (2) followed by a meaningful opportunity for the public to comment on the rule's content; and (3) publication of the final rule not less than 30 days before its effective date. The APA provides that notice and comment procedures do not apply if the agency for good cause finds them to be ''unnecessary, impracticable, or contrary to the public interest.''[8] Section 553(d) of the APA also provides that publication at least 30 days prior to a rule's effective date is not required for (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) a rule for which the agency finds good cause for shortened notice and publishes its reasoning with the rule.[9]

The Board has determined that good cause exists for finding that the notice, public comment, and delayed effective date provisions of the APA are unnecessary, impracticable, or contrary to the public interest with respect to these final amendments to Regulation D. The rate decreases for IORR and IOER that are reflected in the final amendments to Regulation D were made with a view towards accommodating commerce and business and with regard to their bearing upon the general credit situation of the country. Notice and public comment would prevent the Board's action from being effective as promptly as necessary in the public interest and would not otherwise serve any useful purpose. Notice, public comment, and a delayed effective date would create uncertainty about the finality and effectiveness of the Board's

[1] 12 U.S.C. 461(b).

[2] 12 CFR 204.5(a)(1).

[3] 12 U.S.C. 461(b)(1)(A) and (b)(12)(A).

[4] See 12 U.S.C. 461(b)(1)(A) and (b)(12)(C); see also 12 CFR 204.2(y).

[5] See 12 U.S.C. 461(b)(12)(B).

[6] See 12 CFR 204.10(b)(5).

[7] 5 U.S.C. 551 *et seq.*

[8] 5 U.S.C. 553(b)(3)(A).

[9] 5 U.S.C. 553(d).

action and undermine the effectiveness of that action. Accordingly, the Board has determined that good cause exists to dispense with the notice, public comment, and delayed effective date procedures of the APA with respect to these final amendments to Regulation D.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA'') does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[10] As noted previously, the Board has determined that it is unnecessary and contrary to the public interest to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (''PRA'') of 1995,[11] the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

List of Subjects in 12 CFR Part 204

Banks, Banking, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board amends 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 461, 601, 611, and 3105.

■ 2. Section 204.10 is amended by revising paragraph (b)(5) to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

(b) * * *

(5) The rates for IORR and IOER are:

	Rate (percent)
IORR	2.35
IOER	2.35

* * * * *

[10] 5 U.S.C. 603, 604.

[11] 44 U.S.C. 3506; see 5 CFR part 1320 Appendix A.1.

By order of the Board of Governors of the Federal Reserve System, May 7, 2019.

Ann Misback,

Secretary of the Board.

[FR Doc. 2019–09687 Filed 5–9–19; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0903; Product Identifier 2018–NM–113–AD; Amendment 39–19616; AD 2019–07–05]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an airworthiness directive (AD) that published in the **Federal Register.** That AD applies to all Airbus SAS Model A318 series airplanes; Model A319 series airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. As published, that AD contains an incomplete compliance time for the initial inspection for certain airplanes. This document corrects that error. In all other respects, the original document remains the same.

DATES: This correction is effective May 24, 2019.

The effective date of AD 2019–07–05 remains May 24, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of May 24, 2019 (84 FR 16386, April 19, 2019).

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0903.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0903; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

SUPPLEMENTARY INFORMATION: AD 2019–07–05, Amendment 39–19616 (84 FR 16386, April 19, 2019) (''AD 2019–07–05''), currently requires repetitive inspections for cracking of the 10VU rack fitting lugs, and repair of any cracking. That AD applies to all Airbus SAS Model A318 series airplanes; Model A319 series airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

Need for the Correction

As published, table 1 to paragraph (h)(1) of AD 2019–07–05 contains an incomplete compliance time. The first row in table 1 to paragraph (h)(1) of AD 2019–07–05 inadvertently omitted certain clarifying compliance-time language (*i.e.,* ''whichever occurs first'') to distinguish the initial compliance thresholds. The intent of AD 2019–07–05 was to match the content and intent of European Aviation Safety Agency (EASA) AD 2018–0131, dated June 19, 2018, which provides the complete compliance threshold. In addition, the substance of paragraph (h)(1) of AD 2019–07–05 was retained from superseded AD 2016–19–14, Amendment 39–18663 (81 FR 71602, October 18, 2016).

Related Service Information Under 1 CFR Part 51

AD 2019–07–05 requires Airbus Service Bulletins A320–92–1087, Revision 03, dated July 31, 2017; and A320–92–1119, dated July 28, 2017; which the Director of the Federal Register approved for incorporation by reference as of May 24, 2019 (84 FR

16386, April 19, 2019). This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Correction of Publication

This document corrects an error and correctly adds the AD as an amendment to 14 CFR 39.13. Although no other part of the preamble or regulatory information has been corrected, we are publishing the entire rule in the **Federal Register.**

The effective date of this AD remains May 24, 2019.

Since this action only corrects an incomplete compliance time, it has no adverse economic impact and imposes no additional burden on any person. Therefore, we have determined that notice and public procedures are unnecessary.

List of Subjects in 14 CFR Part 39

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

Adoption of the Correction

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Corrected]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–19–14, Amendment 39–18663 (81 FR 71602, October 18, 2016), and adding the following new AD:

2019–07–05 Airbus SAS: Amendment 39–19616; Docket No. FAA–2018–0903; Product Identifier 2018–NM–113–AD.

(a) Effective Date

The effective date of this AD is May 24, 2019.

(b) Affected ADs

This AD replaces AD 2016–19–14, Amendment 39–18663 (81 FR 71602, October 18, 2016) (''AD 2016–19–14'').

(c) Applicability

This AD applies to the Airbus SAS airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Model A318–111, -112, -121, and -122 airplanes.

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

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

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

(d) Subject

Air Transport Association (ATA) of America Code 92, Electric and Electronic Common Installation.

(e) Reason

This AD was prompted by a report of cracks found during maintenance inspections on certain 10VU rack fitting lugs. We are issuing this AD to address reading difficulties of flight-critical information displayed to the flightcrew during a critical phase of flight, such as an approach or takeoff, which could result in loss of airplane control at an altitude insufficient for recovery.

(f) Compliance

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

(g) Definitions

For the purpose of this AD, Group 1 airplanes are in a pre-Airbus Modification 35869 configuration, and Group 2 airplanes are in a post-Airbus Modification 35869 configuration.

(h) Repetitive Inspections

(1) For Group 1 airplanes: At the later of the times specified in table 1 to paragraph (h)(1) of this AD, and thereafter at intervals not to exceed 20,000 flight cycles or 40,000 flight hours, whichever occurs first, do a detailed inspection for cracking of the 10VU rack fitting lugs, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–92–1087, Revision 03, dated July 31, 2017.

Table 1 to paragraph (h)(1) of this AD – *Initial inspection compliance time for Group 1 airplanes*

Compliance Time (whichever occurs later, A or B)	
A	Prior to exceeding 30,000 total flight cycles or 60,000 total flight hours, whichever occurs first
B	Within 24 months after November 22, 2016 (the effective date of AD 2016-19-14)

(2) For Group 2 airplanes: At the later of the times specified in paragraphs (h)(2)(i) and (h)(2)(ii) of this AD, and thereafter at intervals not to exceed 20,000 flight cycles or 40,000 flight hours, whichever occurs first, do a detailed inspection for cracking of the 10VU rack fitting lugs, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–92–1119, dated July 28, 2017.

(i) Prior to exceeding 30,000 total flight cycles or 60,000 total flight hours, whichever occurs first.

(ii) Within 30 days after the effective date of this AD.

(i) Repair

If any crack is found during any inspection required by paragraph (h)(1) or (h)(2) of this AD: Before further flight, do a repair in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–92–1087, Revision 03, dated July 31, 2017 (for Group 1 airplanes); or Service Bulletin A320–92–1119, dated July 28, 2017 (for Group 2 airplanes); as applicable. Repair of a 10VU rack fitting lug does not terminate the repetitive inspections required by paragraphs (h)(1) and (h)(2) of this AD.

(j) Reporting

At the applicable time specified in paragraph (j)(1) or (j)(2) of this AD: Submit a report of findings (positive and negative) of each inspection required by paragraph (h) of this AD to Airbus Service Bulletin Reporting Online Application on Airbus World (*https://w3.airbus.com/*), or submit the results to Airbus in accordance with the instructions of Airbus Service Bulletin A320–92–1087, Revision 03, dated July 31, 2017 (for Group 1 airplanes); or Service Bulletin A320–92–1119, dated July 28, 2017 (for Group 2 airplanes); as applicable. Where Figure A–FAAAA, Sheet 02, of Appendix 01, ''Inspection Report,'' of Airbus Service

Bulletin A320–92–1087, Revision 03, dated July 31, 2017; and Figure A–FAAAA, Sheet 02, of Appendix 01, ''Inspection Report,'' of Service Bulletin A320–92–1119, dated July 28, 2017; specifies sending removed lugs to Airbus for investigation, this AD does not include that requirement.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 90 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 90 days after the effective date of this AD.

(k) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (h)(1) and (i) of this AD if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–92–1087, Revision 02, dated November 25, 2014.

(l) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(m) Other FAA AD Provisions

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

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

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

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0131, dated June 19, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0903.

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

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

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on May 24, 2019 (84 FR 16386, April 19, 2019).

(i) Airbus Service Bulletin A320–92–1087, Revision 03, dated July 31, 2017.

(ii) Airbus Service Bulletin A320–92–1119, dated July 28, 2017.

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

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

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

Issued in Des Moines, Washington, on May 3, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–09680 Filed 5–9–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0334]

RIN 1625–AA00

Safety Zone; Upper Mississippi River, Miles 179 to 184, St. Louis, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the Upper Mississippi River from mile marker (MM) 179 to MM 184 in St. Louis, MO. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters as a result of increasing flow and high water conditions on the river. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

DATES: This rule is effective without actual notice from May 10, 2019 through June 2, 2019. For the purposes of enforcement, actual notice will be used from May 2, 2019, through May 10, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0334 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Christian Barger, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email *Christian.J.Barger@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Upper Mississippi River
DHS Department of Homeland Security

FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
USACE United States Army Corps of Engineers
U.S.C. United States Code
UMR Upper Mississippi River
WAP Waterways Action Plan

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. It is impracticable because we must establish this safety zone immediately and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone and compromise public safety.

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

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with flood waters exist in the St. Louis Harbor of the Upper Mississippi River. Increased flow rates and river height makes navigating this area extremely difficult due to a high number of highway and railroad bridges in the area. This rule is necessary to ensure the safety of persons, vessels, and the marine environment on these navigable waters.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from May 2, 2019 through June 2, 2019, or until cancelled by the COTP, whichever occurs first. The safety zone will cover all navigable waters of the Upper Mississippi River from MM 179 to MM 184, unless reduced in scope by the COTP as flood conditions warrant.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the emergency nature of the action and the increasing flow rates and river height. When the Upper Mississippi River gauge in St. Louis, MO reaches 38 feet above zero, increased flow rates and vertical clearances associated with bridges in the St. Louis area between MM 179 and MM 184 result in difficulty with making safe approaches to the bridges and increase the potential for bridge strikes. Moreover, the Coast Guard will issue a BNM via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone on a case-by-case basis.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone prohibiting entry on a five mile stretch of the Upper Mississippi River that is experiencing significant flooding. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0334 to read as follows:

§ 165.T08–0334 Safety Zone; Upper Mississippi River, Miles 179–184, St. Louis, MO.

(a) *Location.* The following area is a safety zone: All navigable waters of the Upper Mississippi River from mile marker (MM) 179 to MM 184. This section will be enforced on all navigable waters of the Upper Mississippi River from MM 179 to MM 184, unless reduced in scope by the Captain of the Port Sector Upper Mississippi River (COTP) as flood conditions warrant.

(b) *Effective period.* This rule is effective without actual notice from May 10, 2019 until June 2, 2019, or until cancelled by the COTP, whichever occurs first. For the purposes of enforcement, actual notice will be provided from May 2, 2019, until May 10, 2019.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: May 2, 2019.

S.A. Stoermer,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2019–09645 Filed 5–9–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0292]

Safety Zones; Recurring Safety Zones in Captain of the Port Sault Sainte Marie—Mackinaw Area Visitors Bureau Friday Night Fireworks

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce certain safety zones for the Mackinaw Area Visitors Bureau Friday Night Fireworks in Mackinaw City, Michigan, starting in May, 2019 to provide for the safety of life on navigable waterways. This action is necessary and intended to protect the safety of life and property on navigable waters prior to, during, and immediately after these events. During the enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Sault Sainte Marie or a designated representative.

DATES: The regulations in 33 CFR 165.918 will be enforced for safety zone (1), Table 165.918, from 9 p.m. through 11:59 p.m. each Friday, or Saturday in case of inclement weather, from May 17, 2019, through August 30, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST2 Blackledge, Waterways Management, Coast Guard Sector Sault Sainte Marie, U.S. Coast Guard; telephone (906) 253–2443, email *Onnalee.A.Blackledge@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Mackinaw Area Visitors Bureau Friday Night Fireworks safety zones listed as item (1) in Table 165.918 of 33 CFR 165.918 from 9 p.m. through 11:19 p.m. every Friday, or Saturday in case of inclement weather, from May 17, 2019 through August 30, 2019.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Sault Sainte Marie or a designated on-scene representative. Those seeking permission to enter the safety zone may request permission from the Captain of Sault Sainte Marie via channel 16, VHF–FM. Vessels and persons granted permission to enter the safety zone shall obey the directions of the Captain of the Port Sault Sainte Marie or his designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice of enforcement is issued under authority of 33 CFR 165.918, Safety Zones; Recurring safety zones in Captain of the Port Sault Sainte Marie zone, and 5 U.S.C. 552(a). In addition to this publication in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Sault Sainte Marie determines that the safety zone need not be enforced for the full duration stated in this notice he or she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: April 3, 2019.

P.S. Nelson,

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

[FR Doc. 2019–09647 Filed 5–9–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0171]

RIN 1625–AA00

Safety Zone; Illinois River, Miles 0 to 187, Grafton, IL to Peoria, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the Illinois River from mile marker (MM) 0 to MM 187 between Grafton, IL and Peoria, IL. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters as a result of increasing flood conditions on the river that threaten to overtop levees. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

DATES: This rule is effective without actual notice from May 10, 2019 through June 6, 2019. For the purposes of enforcement, actual notice will be used from May 6, 2019, through May 10, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0171 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Christian Barger, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email *Christian.J.Barger@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Upper Mississippi River
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
USACE United States Army Corps of Engineers
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. It is impracticable because we must establish this safety zone immediately and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to public interest because immediate action is necessary to respond to the potential safety hazards associated with floodwaters threatening to overtop levees along the river.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with flood waters threaten to overtop levees along the river due to reports that vessel traffic in the affected area is causing water to overtop levees resulting in increased damage to the levees and flooding impacts to local communities and residential areas. This rule is necessary to ensure the safety of persons, vessels, and the marine environment on these navigable waters due to the flood impacts to USACE levees.

IV. Discussion of the Rule

On May 5, 2019, Coast Guard Sector Upper Mississippi River received multiple reports from the Illinois State Emergency Operations Center and private citizens located along the Illinois River between mile marker (MM) 0 at Grafton, IL and MM 187 at Peoria, IL of water surge impacts from vessel traffic on the Illinois River overtopping levees resulting in damage to the levees and increased flooding.

The COTP has determined that the sudden increase in flood waters approaching the tops of levees along the Illinois River poses a hazard to the safety of persons, vessels, and the marine environment as a result of floodwaters overtopping the levees. This rule establishes a temporary safety zone from May 6, 2019 until June 6, 2019, or until cancelled by the COTP, whichever occurs first. The safety zone will cover all navigable waters of the Illinois River from MM 0 to MM 187, unless reduced in scope by the COTP as flood conditions warrant.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the emergency nature of the action. Moreover, the Coast Guard will issue a BNM via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone on a case-by-case basis to minimize the impacts of this rule.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone prohibiting entry on a one hundred eighty one mile stretch of the Illinois River that is experiencing significant flooding that is impacting levees. It is categorically excluded from further review under

paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. Because this regulation is for a temporary safety zone established to deal with an emergency, and which is longer than one week in duration, a Record of Environmental Consideration is not required at this time, but will be made available in the Docket after the issuance of this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0171 to read as follows:

§ 165.T08–0171 Safety Zone; Illinois River, Miles 0–187, Grafton, IL to Peoria, IL.

(a) *Location.* The following area is a safety zone: all navigable waters of the Illinois River from mile marker (MM) 0 to MM 187, unless reduced in scope by the Captain of the Port Sector Upper Mississippi River (COTP) as flood conditions warrant.

(b) *Effective period.* This rule is effective without actual notice from May 10, 2019 until June 6, 2019, or until cancelled by the COTP, whichever occurs first. For the purposes of enforcement, actual notice will be provided from 5 p.m. on May 6, 2019, until May 10, 2019.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: May 6, 2019.

S.A. Stoermer,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2019–09656 Filed 5–9–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R04–RCRA–2019–0768; FRL–9993–42–Region 4]

Florida: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final authorization.

SUMMARY: The Environmental Protection Agency (EPA) is granting Florida final authorization for changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Agency published a Proposed rule on February 22, 2019, and provided for public comment. The Agency received two comments in support of authorizing the Florida program changes. These comments can be reviewed in the docket for this action under Docket ID No. EPA–R04–RCRA–2019–0768. No further opportunity for comment will be provided.

DATES: This final authorization is effective May 10, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R04–RCRA–2019–0768. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Leah Davis, Materials and Waste Management Branch, RCR Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960; telephone number: (404) 562–8562; fax number: (404) 562–9964; email address: *davis.leah@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. What changes to Florida's hazardous waste program is EPA authorizing with this action?

Florida submitted a complete program revision application, dated August 31, 2018, seeking authorization of changes to its hazardous waste program in accordance with 40 CFR 271.21. EPA now makes a final decision that Florida's hazardous waste program revisions that are being authorized are equivalent to, consistent with, and no less stringent than the Federal program, and therefore satisfy all of the requirements necessary to qualify for final authorization. For a list of State rules being authorized with this Final Authorization, please see the Proposed rule published in the February 22, 2019, **Federal Register** at 84 FR 5650.

B. What is codification and is EPA codifying Florida's hazardous waste program as authorized in this rule?

Codification is the process of placing citations and references to the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by adding those citations and references to the authorized State rules in 40 CFR part 272. EPA is not codifying the authorization of Florida's revisions at this time. However, EPA reserves the ability to amend 40 CFR part 272, subpart K, for the authorization of Florida's program changes at a later date.

C. Statutory and Executive Order Reviews

This final authorization revises Florida's authorized hazardous waste

management program pursuant to Section 3006 of RCRA and imposes no requirements other than those currently imposed by State law. For further information on how this authorization complies with applicable executive orders and statutory provisions, please see the Proposed rule published in the February 22, 2019 **Federal Register** at 84 FR 5650. The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document 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 in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final action will be effective May 10, 2019.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: May 1, 2019.

Mary S. Walker,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–09690 Filed 5–9–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1986–0005; FRL–9993–34–Region 9]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Beckman Instruments Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 9 announces the deletion of the soil portion of the Beckman Instruments Superfund Site (Site) located in Porterville, California, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This partial deletion pertains to the soil portion of the Site. The groundwater will remain on the NPL and is not being considered for deletion as part of this action. EPA and the State of California, through the Department of Toxic Substances Control, have determined that all appropriate response actions under CERCLA have been completed. However, the deletion of the soil portion of the Site does not preclude future actions under Superfund.

DATES: This action is effective May 10, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–1986–0005. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *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 through *http://www.regulations.gov* or at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

Superfund Records Center, 75 Hawthorne Street, Room 3110, San Francisco, California, Hours: 8 a.m.–4 p.m.; (415) 947–8717.

Site Repository: 41 W. Thurman Avenue, Porterville, California. Call (559) 784–0177 for hours of operation.

FOR FURTHER INFORMATION CONTACT: Holly Hadlock, Superfund Project Manager, U.S. EPA, Region 9, (SFD–7–3), 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3171, email: *hadlock.holly@epa.gov.*

SUPPLEMENTARY INFORMATION: The portion of the Site to be deleted from the NPL is the soil at the Beckman Instruments Superfund Site, Porterville, California. A Notice of Intent for Partial Deletion for this Site was published in the **Federal Register** (84 FR 4033–4035) on February 14, 2019. The closing date for comments on the Notice of Intent for Partial Deletion was March 18, 2019. EPA received two comments that support the decision to deletion the soil from the NPL. These comments have been placed in both the docket at *www.regulations.gov* (EPA–HQ–SFUND–1986–0005) and in the repositories listed above.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion of a site from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of portions of a site from the NPL does not affect responsible party liability, in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: April 3, 2019.

Michael B. Stoker,

Regional Administrator, Region 9.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by removing the California entry for ''Beckman Instruments (Porterville Plant)'' and adding an entry for ''Beckman Instruments'' in its place to read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/County	Notes (a)
* * * * * * *			
CA	Beckman Instruments	Porterville	P.
* * * * * * *			
* * * * * * *			
* * * * * * *			
* * * * * * *			

(a) = Based on issuance of health advisory by Agency for Toxic Substances and Disease Registry (if scored, HRS score need not be greater than or equal to 28.50).

* * * * * * *

*P = Sites with partial deletion(s).

[FR Doc. 2019–09480 Filed 5–9–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 401 and 404

[USCG–2018–0665]

RIN 1625–AC49

Great Lakes Pilotage Rates—2019 Annual Review and Revisions to Methodology

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: In accordance with the Great Lakes Pilotage Act of 1960, the Coast Guard is establishing new base pilotage rates and surcharges for the 2019 shipping season. This rule will adjust the pilotage rates to account for a rolling ten-year average for traffic, and result in an increase in pilotage rates due to an adjustment for anticipated inflation, changes in operating expenses, surcharges for applicant pilots, and an addition of two pilots.

DATES: This rule is effective June 10, 2019.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Mr. Brian Rogers, Commandant (CG–WWM–2), Coast Guard; telephone 202–372–1535, email *Brian.Rogers@uscg.mil,* or fax 202–372–1914.

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I. Abbreviations

AMO American Maritime Officers
APA American Pilots Association
BLS Bureau of Labor Statistics
CAD Canadian dollars
CFR Code of Federal Regulations
CPA Certified public accountant
CPI Consumer Price Index
DHS Department of Homeland Security
FOIA Freedom of Information Act
FOMC Federal Open Market Committee
FR Federal Register
GLPA Great Lakes Pilotage Authority (Canadian)
GLPAC Great Lakes Pilotage Advisory Committee
GLPMS Great Lakes Pilotage Management System
ICR Information Collection Request
LIBOR London Interbank Offered Rate
NAICS North American Industry Classification System
NPRM Notice of proposed rulemaking
NTSB National Transportation Safety Board
OIRA Office of Information and Regulatory Affairs
OMB Office of Management and Budget
PCE Personal Consumption Expenditures
SBA Small Business Administration
§ Section symbol
SLSMC Saint Lawrence Seaway Management Corporation
The Act Great Lakes Pilotage Act of 1960
U.S.C. United States Code
USD United States dollars
WGLPA Western Great Lakes Pilot Association

II. Executive Summary

Pursuant to the Great Lakes Pilotage Act of 1960 (''the Act''),[1] the Coast Guard regulates pilotage for oceangoing vessels on the Great Lakes—including setting the rates for pilotage services and adjusting them on an annual basis. The rates, which during the 2018 shipping year ranged from $271 to $653 per pilot hour (depending on the specific area where pilotage service is provided), are paid by shippers to pilot associations. The three pilot associations are the exclusive U.S. source of registered pilots on the Great Lakes. The pilot associations use this revenue to cover operating expenses, maintain infrastructure, compensate working pilots, and train new pilots. Since 2016, the Coast Guard has used a ratemaking methodology that was developed in accordance with our statutory requirements and regulations. This ratemaking methodology calculates the revenue needed for each pilotage association (including operating expenses, compensation, and infrastructure needs), and then divides that amount by the 10-year average of shipping traffic to produce an hourly rate. This process is currently effected through a 10-step methodology and supplemented with surcharges, which are explained in detail in this rulemaking.

In this final rule, the Coast Guard is establishing new pilotage rates for 2019 based on the existing ratemaking methodology. As proposed in the notice of proposed rulemaking (NPRM), the Coast Guard is adjusting the rates to account for 2019 inflation, the addition of two working pilots, and updated historic traffic data. Based on the comments to the NPRM, the Coast Guard is also adjusting the operating expenses and correcting previous traffic data, which is discussed in Section V below. The result of these changes is an overall increase in the rates, as shown in Table 1.

TABLE 1—CURRENT AND NEW PILOTAGE RATES ON THE GREAT LAKES

Area	Name	2018 Pilotage rate	Proposed 2019 pilotage rate	Final 2019 pilotage rate
District One: Designated	St. Lawrence River	$653	$698	$733
District One: Undesignated	Lake Ontario	435	492	493
District Two: Undesignated	Lake Erie	497	530	531
District Two: Designated	Navigable waters from Southeast Shoal to Port Huron, MI.	593	632	603
District Three: Undesignated	Lakes Huron, Michigan, and Superior	271	304	306
District Three: Designated	St. Mary's River	600	602	594

This final rule is not economically significant under Executive Order 12866. This rule impacts 51 United States Great Lakes pilots, 3 pilot associations, and the owners and operators of an average of 256 oceangoing vessels that transit the Great Lakes annually. The estimated overall annual regulatory economic impact of this rate change is a net increase of $2,831,743 in payments made by shippers from the 2018 shipping season. Because the Coast Guard must review, and, if necessary, adjust rates each year, the rates are analyzed as single year costs and are not annualized over 10 years. This rule does not affect the Coast Guard's budget or increase Federal spending. Section VII of this preamble provides the regulatory impact analyses of this final rule.

III. Basis and Purpose

The legal basis of this rulemaking is the Great Lakes Pilotage Act of 1960 (''the Act''),[2] which requires U.S. vessels operating on register and foreign vessels to use U.S. or Canadian registered pilots while transiting the U.S. waters of the St. Lawrence Seaway and the Great Lakes system.[3] For the U.S. registered Great Lakes pilots (''pilots''), the Act requires the Secretary to ''prescribe by regulation rates and charges for pilotage services, giving consideration to the public interest and the costs of providing the services.''[4] The Act requires that rates be established or reviewed and adjusted each year, no later than March 1. The Act requires that base rates be established by a full ratemaking at least once every five years, and in years when base rates are not established, the rates must be reviewed and, if necessary, adjusted. The Secretary's duties and authority under the Act have been delegated to the Coast Guard.[5]

This final rule establishes new pilotage rates and surcharges for the 2019 shipping season. The Coast Guard believes that the new rates will promote pilot retention, ensure safe, efficient, and reliable pilotage services on the Great Lakes, and provide adequate funds to upgrade and maintain infrastructure.

IV. Background

Pursuant to the Great Lakes Pilotage Act of 1960, the Coast Guard, in conjunction with the Canadian Great Lakes Pilotage Authority, regulates shipping practices and rates on the Great Lakes. Under Coast Guard regulations, all vessels engaged in foreign trade (often referred to as ''salties'') are required to engage U.S. or Canadian pilots during their transit through the regulated waters.[6] United States and Canadian ''lakers,'' which account for most commercial shipping on the Great Lakes, are not affected.[7] Generally, vessels are assigned a U.S. or Canadian pilot depending on the order in which they transit a particular area of the Great Lakes and do not choose the pilot they receive. If a vessel is assigned a U.S. pilot, that pilot will be assigned by the pilotage association responsible for the particular district in which the vessel is operating, and the vessel operator will pay the pilotage association for the pilotage services.

The U.S. waters of the Great Lakes and the St. Lawrence Seaway are divided into three pilotage districts. Pilotage in each district is provided by an association certified by the Coast Guard's Director of the Great Lakes Pilotage (''the Director'') to operate a pilotage pool. The Saint Lawrence Seaway Pilotage Association provides

[1] Title 46 United States Code (U.S.C.) Chapter 93; Public Law 86–555, 74 Stat. 259, as amended.

[2] 46 U.S.C. chapter 93; Public Law 86–555, 74 Stat. 259, as amended.

[3] 46 U.S.C. 9302(a)(1).

[4] 46 U.S.C. 9303(f).

[5] Department of Homeland Security (DHS) Delegation No. 0170.1, para. II (92.f).

[6] See 46 CFR part 401.

[7] 46 U.S.C. 9302(f). A ''laker'' is a commercial cargo vessel especially designed for and generally limited to use on the Great Lakes.

pilotage services in District One, which includes all U.S. waters of the St. Lawrence River and Lake Ontario. The Lakes Pilotage Association provides pilotage services in District Two, which includes all U.S. waters of Lake Erie, the Detroit River, Lake St. Clair, and the St. Clair River. The Western Great Lakes Pilotage Association provides pilotage services in District Three, which includes all U.S. waters of the St. Mary's River; Sault Ste. Marie Locks; and Lakes Huron, Michigan, and Superior.

Each pilotage district is further divided into ''designated'' and ''undesignated'' areas. Designated areas are classified as such by Presidential Proclamation [8] to be waters in which pilots must, at all times, be fully engaged in the navigation of vessels in their charge. Undesignated areas, on the other hand, are open bodies of water, and thus are not subject to the same pilotage requirements. While working in those undesignated areas, pilots must ''be on board and available to direct the navigation of the vessel at the discretion of and subject to the customary authority of the master.'' [9] For pilotage purposes, rates in designated areas are significantly higher than those in undesignated areas for these reasons.

TABLE 2—AREAS OF THE GREAT LAKES AND SAINT LAWRENCE SEAWAY

District	Pilotage association	Designation	Area No.[10]	Area name[11]
One	Saint Lawrence Seaway Pilotage Association.	Designated	1	St. Lawrence River.
		Undesignated	2	Lake Ontario.
Two	Lake Pilotage Association	Designated	5	Navigable waters from Southeast Shoal to Port Huron, MI.
		Undesignated	4	Lake Erie.
Three	Western Great Lakes Pilotage Association.	Designated	7	St. Mary's River.
		Undesignated	6	Lakes Huron and Michigan.
		Undesignated	8	Lake Superior.

Each pilot association is an independent business and is the sole provider of pilotage services in the district in which it operates. Each pilot association is responsible for funding its own operating expenses, maintaining infrastructure, acquiring and implementing technological advances, training personnel or partners and pilot compensation. The Coast Guard developed a 10-step ratemaking methodology to derive a pilotage rate that covers these expenses based on the estimated amount of traffic. The methodology is designed to measure how much revenue each pilotage association will need to cover expenses and provide competitive compensation to working pilots. The Coast Guard then divides that amount by the historical average traffic transiting through the district.

Over the past three years, the Coast Guard has made adjustments to the Great Lakes pilotage ratemaking methodology. In 2016, we made significant changes to the methodology, moving to an hourly billing rate for pilotage services and changing the compensation benchmark to a more transparent model. In 2017, we added additional steps to the ratemaking methodology, including new steps that accurately account for the additional revenue produced by the application of weighting factors (discussed in detail in Steps 7 through 9 of this preamble). In 2018, we revised the methodology by which we develop the compensation benchmark, based upon the rate of U.S. mariners rather than Canadian registered pilots. The 2018 methodology, which was finalized in the June 5, 2018 final rule (83 FR 26162) and is the current methodology, is designed to accurately capture all of the costs and revenues associated with Great Lakes pilotage requirements and produce an hourly rate that adequately and accurately compensates pilots and covers expenses. The current methodology is summarized in the section below.

Summary of Ratemaking Methodology

As stated above, the ratemaking methodology, currently outlined in 46 CFR 404.101 through 404.110, consists of 10 steps that are designed to account for the revenues needed and total traffic expected in each district. The result is an hourly rate, determined separately for each of the areas administered by the Coast Guard.

In Step 1, ''Recognize previous operating expenses,'' (§ 404.101), the Director reviews audited operating expenses from each of the three pilotage associations. This number forms the baseline amount that each association is budgeted. Because of the time delay between when the association submits raw numbers and the Coast Guard receives audited numbers, this number is three years behind the projected year of expenses. In calculating the 2019 rates, the Coast Guard used the audited expenses from fiscal year 2016.

While each pilotage association operates in an entire district, the Coast Guard determines costs by area. Thus, with regard to operating expenses, the Coast Guard allocates certain operating expenses to undesignated areas, and certain expenses to designated areas. In some cases (*e.g.,* insurance for applicant pilots who operate in undesignated areas only), we allocate based on where they are actually accrued. In other situations (*e.g.,* general legal expenses), expenses are distributed between designated and undesignated waters on a *pro rata* basis, based upon the proportion of income forecasted from the respective portions of the district.

In Step 2, ''Project operating expenses, adjusting for inflation or deflation,'' (§ 404.102), the Director develops the 2019 projected operating expenses. To do this, we apply inflation adjustors for three years to the operating expense baseline received in Step 1. The inflation factors used are from the Bureau of Labor Statistics (BLS) Consumer Price Index (CPI) for the Midwest Region, or, if not available, the Federal Open Market Committee (FOMC) median economic projections for Personal Consumption Expenditures (PCE) inflation. This step produces the

[8] Presidential Proclamation 3385, *Designation of Restricted Waters Under the Great Lakes Pilotage Act of 1960,* December 22, 1960.

[9] 46 U.S.C. 9302(a)(1)(B).

[10] Area 3 is the Welland Canal, which is serviced exclusively by the Canadian GLPA and, accordingly, is not included in the United States pilotage rate structure.

[11] The areas are listed by name in the Code of Federal Regulations, see 46 CFR 401.405.

total operating expenses for each area and district.

In Step 3, ''Estimate number of working pilots,'' (§ 404.103), the Director calculates how many pilots are needed for each district. To do this, we employ a ''staffing model,'' described in § 401.220, paragraphs (a)(1) through (3), to estimate how many pilots would be needed to handle shipping during the beginning and close of the season. This number is helpful in providing guidance to the Director in approving an appropriate number of credentials for pilots.

For the purpose of the ratemaking calculation, we determine the number of working pilots provided by the pilotage associations (see § 404.103) which is what we use to determine how many pilots need to be compensated via the pilotage fees collected.

In Step 4, ''Determine target pilot compensation benchmark,'' (§ 404.104), the Director determines the revenue needed for pilot compensation in each area and district. This step contains two processes. In the first process, we calculate the total compensation for each pilot using a ''compensation benchmark.'' Next, we multiply the individual pilot compensation by the number of working pilots for each area and district (from Step 3), producing a figure for total pilot compensation. Because pilots are paid by the associations, but the costs of pilotage are divided up by area for accounting purposes, we assign a certain number of pilots for the designated areas and a certain number of pilots for the undesignated areas for purposes of determining the revenues needed for each area. To make the determination of how many pilots to assign, we use the staffing model designed to determine the total number of pilots described in Step 3, above.

In the second process of Step 4, set forth in § 404.104(c), the Director determines the total compensation figure for each District. To do this, the Director multiplies the compensation benchmark by the number of working pilots for each area and district (from Step 3), producing a figure for total pilot compensation.

In Step 5, ''Project working capital fund,'' (§ 404.105), the Director calculates a value that is added to pay for needed capital improvements. This value is calculated by adding the total operating expenses (derived in Step 2) and the total pilot compensation (derived in Step 4), and multiplying that figure by the preceding year's average annual rate of return for new issues of high-grade corporate securities. This figure constitutes the ''working capital fund'' for each area and district.

In Step 6, ''Project needed revenue,'' (§ 404.106), the Director adds up the totals produced by the preceding steps. For each area and district, we add the projected operating expense (from Step 2), the total pilot compensation (from Step 4), and the working capital fund contribution (from Step 5). The total figure, calculated separately for each area and district, is the ''revenue needed.''

In Step 7, ''Calculate initial base rates,'' (§ 404.107), the Director calculates an hourly pilotage rate to cover the revenue needed, as calculated in step 6. This step consists of first calculating the 10-year traffic average for each area. Next, we divide the revenue needed in each area (calculated in Step 6) by the 10-year traffic average to produce an initial base rate.

An additional element, the ''weighting factor,'' is required under § 401.400. Pursuant to that section, ships pay a multiple of the ''base rate'' as calculated in Step 7 by a number ranging from 1.0 (for the smallest ships, or ''Class I'' vessels) to 1.45 (for the largest ships, or ''Class IV'' vessels). As this significantly increases the revenue collected, we need to account for the added revenue produced by the weighting factors to ensure that shippers are not overpaying for pilotage services.

In Step 8, ''Calculate average weighting factors by area,'' (§ 404.108), the Director calculates how much extra revenue, as a percentage of total revenue, has historically been produced by the weighting factors in each area. We do this by using a historical average of applied weighting factors for each year since 2014, the first year the current weighting factors were applied.

In Step 9, ''Calculate revised base rates,'' (§ 404.109), we modify the base rates by accounting for the extra revenue generated by the weighting factors. We do this by dividing the initial pilotage rate for each area (from Step 7) by the corresponding average weighting factor (from Step 8), to produce a revised rate.

In Step 10, ''Review and finalize rates,'' (§ 404.110), often referred to informally as ''Director's discretion,'' the Director reviews the revised base rates (from Step 9) to ensure that they meet the goals set forth in the Act and 46 CFR 404.1(a), which include promoting efficient, safe, and reliable pilotage service on the Great Lakes; generating sufficient revenue for each pilotage association to reimburse necessary and reasonable operating expenses; compensating pilots fairly and providing appropriate funds for infrastructure and training. The Coast Guard also uses various factors to ensure that the rate is set in the public interest and will continue to encourage robust traffic in the Great Lakes. The Martin Study is one factor the Coast Guard considered when setting rates for shipping, but Coast Guard also recognizes that it is not a comprehensive analysis of all economic factors.[12]

Finally, after the base rates are set, § 401.401 permits the Coast Guard to apply surcharges. Currently, we use surcharges to pay for the training of new pilots rather than incorporating training costs into the overall ''revenue needed'' used in the calculation of the base rates. In recent years, we have allocated $150,000 per applicant pilot to be collected via surcharges. This amount is calculated as a percentage of total revenue for each district, and that percentage is applied to each bill. When the total amount of the surcharge has been collected, the pilot associations are prohibited from collecting further surcharges. Thus, in years where traffic is heavier than expected, shippers early in the season could pay more than shippers employing pilots later in the season, after the surcharge cap has been met.

V. Discussion of Comments

In response to the October 17, 2018, NPRM (83 FR 52355), the Coast Guard received five comment letters. These included one comment from the three Great Lakes pilot associations,[13] one comment from the law firm Thompson Coburn, which represents the interests of the Shipping Federation of Canada, the American Great Lakes Ports Association, and the United States Great Lakes Shipping Association (hereinafter ''User's Coalition''),[14] a comment from the president of the St. Lawrence Seaway Pilots' Association,[15] a comment from the president of the Lakes Pilots Association,[16] and a comment from the president of the Western Great Lakes Pilot Association.[17] As each of these commenters touched on numerous issues, for each response below, we note which commenters raised the specific points addressed. In situations where multiple commenters

[12] Martin Associates, ''Analysis of Great Lakes Pilotage Costs on Great Lakes Shipping and the Potential Impact of Increases in U.S. Pilotage Charges,'' page 33. Available at *http://www.regulations.gov,* USCG–2018–0665–0005.

[13] USCG–2018–0665–0008, available at *http://www.regulations.gov.*

[14] USCG–2018–0665–0010.

[15] USCG–2018–0665–0009.

[16] USCG–2018–0665–0007.

[17] USCG–2018–0665–0006.

raised similar issues, we attempt to provide one response to those issues.

A. Operating Expenses

The first step of the ratemaking process entails establishing the allowable operating expenses for each pilotage district, and allowing pilot associations to recoup any costs that are considered reasonable and necessary for operation of a pilotage association. To do so, pilotage associations submit accounting statements to independent auditors, and then the audited reports are forwarded to the Coast Guard for additional review. We received several comments from pilot associations and persons representing such interests requesting changes to these adjustments, which are discussed below.

a. Medical Benefits Paid to Retired Pilots

The Coast Guard received one comment concerning an adjustment made for payments to retired pilots. In the NPRM, we proposed to disallow $90,600 of requested charges for payments of health benefits for retired pilots. In doing so, we stated that ''we consider health benefits to be 'compensation,' and compensation paid to pilots cannot be recouped as operating expenses.'' [18] One commenter [19] stated that, because the payments were made on behalf of retired pilots who were not among the 13 allowed pilots, the amount should not be considered as pilot compensation and should be construed as a reimbursable operating expense. The commenter also noted that such a payment had been allowed in a 2005 Interim Rule.[20]

Upon examining the enclosed **Federal Register** citation to the 2005 interim final rule and reviewing the regulatory text, the Coast Guard confirms its proposal to disallow payments of health benefits and reaffirms here that medical expenses paid on behalf on pilots should be considered pilot compensation, and not an operating expense. Section 404.2 requires that medical and pension benefits for pilots be treated as pilot compensation; *i.e.,* not as an allowable operating expense. The reasoning in the 2005 **Federal Register** Interim Rule does not apply here. In the 2005 Interim Rule, which was predicated on pre-2016 regulations, the Coast Guard based the decision to expense certain medical costs on the specific contours of the American Maritime Officers (AMO) union contracts that formed the basis of the 2005 compensation benchmark. Such reasoning, even if it were permissible under the current regulations, does not apply to the 2016 operating expenses at issue in this year. Instead of basing our compensation on the AMO contract, the Coast Guard based the 2016 compensation benchmark on Canadian compensation figures.

b. Calculation of Applicant Pilot Costs

One commenter stated that District 3 had misstated its medical expenses in its report to the auditors.[21] The commenter argued that it had submitted an aggregated medical expense of $77,060, and that the auditors had incorrectly allocated all of that sum as costs associated with pilots. The commenter stated that, in fact, $60,031 of that sum was paid as medical expenses for applicant pilots, while only $17,030 (numbers are rounded to the nearest dollar) were paid as partner compensation. They claimed that they had submitted a spreadsheet to the auditors with the correct disaggregated information, but that the auditors had failed to use it.

The Coast Guard agrees with this comment. The Coast Guard consulted with the auditors, who re-examined the information provided to them by District 3. The auditors agreed that information disaggregating the medical expense items had been overlooked, and that the medical expenses of the District 3 applicant pilots had been understated by a total of $60,031. For that reason, the Coast Guard is adding that figure to the total applicant medical expenses for District 3 (see Table 5 below).

In a related note, the adjustment to applicant pilot compensation for District 3 effects the Director's adjustment for District 2 applicant pilot expenses. In the NPRM, the Coast Guard proposed to make a substantial adjustment to the District 2 request for reimbursement of $571,248 for two applicant pilots, as that request was not supported by audited financial statements.[22] Instead of permitting $571,248 for two applicant pilots, we proposed allowing an operating expense of $257,566, or $128,783 per applicant pilot, which was equivalent to the amount paid by District 3 to applicant pilots, resulting in a proposed Director's adjustment of $313,681. However, as we have adjusted the allowance for District 3 applicants by $60,031 for the reasons described above, a similar adjustment is required for the two District 2 applicants. For that reason, we are finalizing a positive $60,031 Director's adjustment for District 2 applicant pilot benefits, in addition to the negative $313,681 adjustment to wages originally proposed, for a total negative adjustment of $253,650 (see Table 5 below).

One commenter provided comments on the District 2 applicant pilot adjustment, and we believe the above change addresses their comment. The commenter stated that in the NPRM, ''the proposed rule training expenses have been denied merely on the ground that they are higher than purported (and incorrectly stated) District 3 expenses.'' [23] While the commenter is incorrect that the Coast Guard did not approve the stated figures *merely* because they were high,[24] we agree with the commenter that the District 3 expenses were inaccurately stated. However, we disagree with the commenter's argument that the District 2 applicant expenses should be accepted at face value. We note that all operating expenses must be ''reasonable in their amounts'' pursuant to section 404.2(c)(1). District 2 asserted, in their letter to the Coast Guard,[25] that they paid applicant pilots $285,624.23 each in wages alone, a number far larger than the applicant salaries of the other Districts and nearly on par with full pilots, which the Coast Guard provided a targeted compensation level of $326,114 (a figure which included full benefits) for 2016. In the NPRM, we stated that ''because this number is far out of line from wages paid to applicant pilots in other districts, as well as the Coast Guard's estimate[s] . . . the Director proposes only allowing a portion of these expenses to be recouped as reasonable operating expenses.'' [26] We remain unpersuaded that $285,624.23 is a reasonable wage for an applicant pilot.

c. Reimbursement for Direct-Billed Pilot Boat Costs

One commenter suggested that the auditor's adjustment for direct-billed pilot boat runs should be reduced. In the NPRM, the Coast Guard noted an auditor's adjustment for $92,056 of direct-billed boat and discharge costs.[27] In District 3, ordinary pilot boat costs are billed to the Western Great Lakes

[18] Great Lakes Pilotage Rates—2019 Annual Review and Revisions to Methodology (October 17, 2018), 83 FR 52355 at 52361.

[19] USCG–2018–0665–0007.

[20] 70 FR 12082, 12086 (March 10, 2005).

[21] USCG–2018–0665–0008, p. 2–3.

[22] See 83 FR 52355, at 52361.

[23] USCG–2018–0665–0008, p.8.

[24] In the NPRM, we stated that we had received inaccurate information on applicant expenses originally, and the unaudited assertion made in response to Coast Guard inquiries was not believed. See 83 FR 52355, at 52361.

[25] USCG–2018–0665–0001.

[26] 83 FR 52355, at 52361.

[27] See item D3–16–02, 83 FR 52355, at 52362.

Pilot Association (WGLPA), and are considered a reimbursable operating expense. However, when a pilot boat is operated for the convenience of the vessel, the cost is billed directly to the vessel and paid to the associations, which reimburse the pilot boat. Thus, the pilotage association cannot claim that cost as a reimbursable operating expense, as that would constitute double-billing. For this reason, the auditor disallowed the recoupment of those fees as operating costs. However, one commenter [28] argued that the auditor erred. Because of that $92,056 billed to the shippers, the Canadian Great Lakes Pilotage Authority (GLPA) had received $37,754 more in revenues from those services than it had paid in costs, and the WGLPA suffered an equivalent shortfall. The WGLPA requested that it be allowed to recoup the $37,754 shortfall as reimbursable operating expenses.

After consideration of the comment, the Coast Guard does not agree that this expense should be included with operating costs. The cost for pilotage boat services was $92,056, which was paid by the shippers at that time. As the commenter stated, while the revenues from $92,056 were split approximately evenly between the GLPA and WGLPA, the WGLPA paid a much larger percentage of the $92,056 in costs, resulting in a $37,754 shortfall for the WGLPA and an equivalent windfall for the GLPA. While the WGLPA is correct that it suffered a loss from this inequitable split, we do not believe that the shortfall should be made up by permitting the WGLPA to bill an additional $37,754 to the shippers, who have already paid the costs for the pilot boat services in full.

d. Housing Allowances

In the NPRM, the Coast Guard proposed to disallow $36,900 in housing allowance expenditures for the District 3 operating expenses. As we did not have documentation of monies spent, we requested that the association ''provide the receipts that could help to determine if these are recoverable operating expenses.'' [29] We also note that the Director is legally prohibited from permitting undocumented expenses pursuant to 46 CFR 404.2(c)(1).

One comment addressed the amount of money paid for housing. This commenter [30] argued that the total sum amounted to $820 per month for 5 pilots, and that this amount was paid to the pilots so they could rent apartments in the De Tour/Sault St. Marie area instead of using hotels when required to stay overnight. The commenter argued that the cost of a hotel in the area is about $95 per night, and that using hotels could cost over $2,000 per month per pilot. While hotel receipts would satisfy the Coast Guard's need for ''receipts,'' the commenter argues using hotels would not be a cost-effective method for housing pilots. The Coast Guard believes that this commenter has placed too much emphasis on the Coast Guard's use of the word ''receipts'' and misinterpreted the requirements of 46 CFR 404.2(c)(1), which prohibits the recoupment of ''undocumented expenses.'' That provision requires documentation of money spent, and does not permit the reimbursement of an ''allowance.'' For example, the Coast Guard would accept leases and documentation of money paid for apartments as an allowable operating expense, assuming it found the expense necessary and reasonable pursuant to section 404.2(a). However, we cannot reimburse an allowance paid to pilots as an operating expense. We require verification for all payments with proper documentation clearly demonstrating that the money was spent on allowable and reasonable expenses. For these reasons, we are denying the request to recoup the housing allowance as an operating expense.[31]

e. Capital Expenses

One commenter stated they submitted costs for ''infrastructure'' to the Coast Guard, and that ''discussions with the Coast Guard at the time indicated the submitted data was sufficient for ratemaking purposes,'' but that the ''NPRM shows no contemplation of removing these funds.'' [32] This comment refers to the ''Capital Acquisitions'' item referred in Section X of the document entitled St. Lawrence Seaway Pilots Association—Independent Accountant's Report on Applying Agreed-Upon Procedures.'' [33] That document describes three properties in New York used by the St. Lawrence Seaway Pilots Association for operational needs. The document stated that the Coast Guard would approve $466,940 in operating costs to cover cash outlays made in 2016 to acquire these properties.[34]

While the Coast Guard originally believed that these outlays would be covered by money brought in from Step 5 of the ratemaking process, we now believe, based on the comment and contemporaneous communication with the association, that this should be considered an operating expense. While future capital acquisitions may or may not be considered operating expenses due to the existence of the working capital fund (see the ''working capital fund'' discussion below for more detailed discussion on treatment of capital expenses), we note that the working capital fund was not in effect at the time of these acquisitions. It was only in 2017 that Step 5 of the ratemaking process was identified as the working capital fund, and until that point, it had been characterized as a ''return on investment.'' Based on that, we believe it within the purview of the Coast Guard to identify which capital expenses are considered reasonable and necessary pursuant to the guidelines in § 404.2, and we believe that these purchases are within those guidelines. For that reason, we are adding the $466,940 property acquisition cost to the allowable operating expenses of District 1.

f. Legal Fees

One commenter suggested that the Coast Guard had erroneously made a Director's adjustment of $1,292 for legal fees for District 3, and that adjustment should be removed.[35] The commenter stated that only $15,208.09 of its reported legal fees were for ''general activities,'' and that it had already excluded 3 percent of that amount from its requested operating expenses as related to lobbying. The Coast Guard has examined the commenter's calculations and agrees the Director's adjustment was unneeded, and has thus removed it.

B. Surcharge Offsets

Beginning in 2016, the Coast Guard began implementing surcharges on shipping rates to encourage the recruitment and training of new pilots on the Great Lakes. Unlike pilot compensation, costs relating to the compensation and training of applicant pilots are fully reimbursable as operating expenses. However, the Coast Guard used surcharges so that pilot associations could receive the money needed to cover the costs of recruiting and training pilots in the year they were incurred, rather than wait three years until such costs could be reimbursed as ordinary operating expenses. As such, the surcharges act as an ''advance'' on

[28] USCG–2018–0665–0006, p.3.

[29] 83 FR 52355, at 52362.

[30] USCG–2018–0665–0006, p. 4.

[31] We note that the commenter describes a situation in which the pilots maintain apartments in the metro area (DeTour/Sault St Marie) in which they work. Under IRS guidance, one cannot claim lodging expenses in the city in which they work.

[32] USCG–2018–0665–0009, p.1.

[33] USCG–2018–0665–0002, p.30.

[34] USCG–2018–0665–0002, p.8, note 2.

[35] USCG–2018–0665–0006, p.3.

the reimbursed operating expenses. This year, 2019, is the first year in which we can view the incurred operating expenses for applicant pilots in 2016, and deduct from operating expenses the actual amounts collected in surcharges. We note that in the 2017 rulemaking, we modified the surcharge provision to limit the amount collected to $150,000 per applicant pilot. However, in 2016, the year to which these calculations apply, there was no cap on the amount of surcharges, and the amounts collected therefore totaled far more than the surcharge percentage was anticipated to collect.

In the NPRM, the Coast Guard included a ''surcharge offset'' line, which corresponded to the actual amount collected in surcharges in the 2016 shipping season.[36] We received several comments on this issue, although some of the commenters appeared to misunderstand what the surcharge adjustment was for or the basis on which it was calculated. One commenter provided information about pilot costs from 2017, stating that ''the Coast Guard should have audited data showing that District Three's surcharge revenue for 2017 was only $382,297.24 of the $600,000 projected applicant pilot cost.'' [37] The commenter's statement refers to the wrong year—the ''surcharge offset'' should be equal to the amount actually collected by surcharges in the year of expenses being analyzed (which for this rule is 2016, not 2017). We will analyze surcharge offsets for subsequent years at the appropriate time, when we consider that year's operating expenses for purposes of rate calculation.

One commenter stated that ''the proposed rule also errs in stating that the $150,000 per pilot surcharge amounts were intended to be hard estimates or caps on the amount of reasonable training expenditures, so that any amounts expended beyond that should now be disallowed.'' [38] While the Coast Guard is uncertain about what statements in the proposed rule the commenter is referring to, we agree that there was no hard limit on how much could be spent on training and stipends for applicant pilots, so long as the expenses were considered to be reasonable and necessary pursuant to the requirements in § 404.2(a). The commenter goes on to state that the NPRM ''proposes to *deduct* from each association's operating expenses not only any surcharges collected in excess of $150,000 per applicant pilot, *id. . . .*'' [39] [40] We disagree with the commenter, and note the ''surcharge offset'' is equal to the actual dollar amount collected as surcharges in the 2016 shipping season. The ''surcharge offset'' is unrelated to whether certain operating costs are deemed necessary and reasonable.

C. Continued Use of Surcharges

In the NPRM, the Coast Guard suggested that we might not continue to use surcharges in future years to cover costs relating to applicant pilots, and instead revert to a system where all costs associated with applicant pilots would be reimbursed through the operating expense provisions. Noting that the ''vast majority of registered pilots are not scheduled to retire in the next 20 years,'' [41] the Coast Guard invited comments on discontinuing the surcharge practice that has been in effect the last three years. We received several responses to this suggestion, all of which opposed the idea. One commenter argued that ''while there has been progress in hiring new pilots nothing suggests that these new hires, many of which have been made to expand the pilotage pool rather than to replace departing pilots, have operated to reduce the need to train replacement pilots for the next two decades.'' [42] Another commenter stated that ''[m]uch as we dislike surcharges—we think the Coast Guard should keep the status quo until it is ready to propose a better solution.'' [43]

Based on the comments received, it appears that various interests on the pilot side support the continued application of surcharges. While no change was proposed for 2019, the Coast Guard will take this stated preference into consideration as we prepare the 2020 ratemaking deliberations.

D. Target Compensation

In the NPRM, the Coast Guard established the target compensation benchmark by multiplying the previous year's compensation benchmark by the estimated inflation for 2018, giving a total of $359,887 per pilot for 2019. We received numerous comments pertaining to this calculation, which are described below.

a. Questions Relating to the Interim Compensation Benchmark

i. Inflation Adjustments From 2015–2018

One commenter raised questions about the use of AMO contracts in the ''interim compensation'' benchmark that the Coast Guard established in the 2018 ratemaking rule.[44] The commenter argued that the Coast Guard's failure to use the actual wage adjustment rates received by the AMO from 2015–2018 was a mistake, and caused the compensation figure to be too low, and demonstrated calculations that would use the contracted increases from the AMO 2015 onward contract to arrive at target compensation figure approximately $10,000 above what the Coast Guard calculated for 2018. This commenter misunderstands the nature of the interim compensation benchmark, which was tied to the AMO contracts in place from 2011–2015. To summarize, the interim compensation benchmark sought to match the daily AMO compensation level from 2015, apply it to the 270-day working season for Great Lakes pilots, and then adjust that number for inflation. It did not seek to match the contract stipulations from 2015 onward, because the Coast Guard did not have access to the underlying contract documents for that period. We discussed the interim compensation benchmark more thoroughly in the 2018 NPRM and final rule. In those documents, we described the interim compensation benchmark as being based on the 2015 AMO rate—and then adjusted for inflation using public inflation data to achieve an equivalent real value for 2018. We stated that we would not use the more recent data on AMO contracts, as we did not have access to the underlying documents. As we still lack that data and have not proposed changing the basis for the compensation benchmark, we cannot adopt the commenter's assertion that we should use contract data from the 2015–2019 AMO contracts.

ii. Use of a 270-Day Multiplier and Guaranteed Overtime Figure

One commenter [45] raised an issue relating to how we translated the daily wage rate from the AMO contract to a yearly compensation for purposes of setting the interim compensation benchmark in 2018. As described in the 2018 ratemaking, the Coast Guard multiplied the daily rate, as calculated using the AMO contracts, by 270 to get the yearly compensation figure. We

[36] See NPRM, 83 FR 52355, at 52359 for additional discussion.

[37] USCG–2018–0665–0006, p.5.

[38] USCG–2018–0665–0008, p.5.

[39] It is unclear what the commenter is citing here, as the previous citation was to the 2016 GLPAC Public Meeting.

[40] USCG–2018–0665–0008, p. 7.

[41] 83 FR 52355, at 52370.

[42] USCG–2018–0665–0008, p.5.

[43] USCG–2018–0665–0006, p.5.

[44] USCG–2018–0665–0008, p.2–3.

[45] USCG–2018–0665–0010, p. 4.

used the figure of 270 days because that is the number of days in the Great Lakes shipping season. However, the commenter argued that the Coast Guard should have multiplied the daily rate by 200, which is the number of days a Great Lakes pilot is actually expected to work under our staffing model, which would result in significantly lower target compensation. The commenter stated that the lower figure ''reflected the reality of the Coast Guard's imposition of a required 10-day per month rest requirement for U.S. pilots.'' [46] The commenter also took issue with the Coast Guard's incorporation of the ''guaranteed overtime'' figure that was incorporated into the rate, stating that the ''Coast Guard accepted this figure at face value and incorporated it in its entirety . . . with no reported inquiry into the validity of this figure.[47]

While the Coast Guard understands the commenter's arguments that these actions by the Coast Guard led to significantly higher target compensation figures, we stand by the reasoning in doing so as articulated in the 2018 final rule. In responding to a similar comment to the 2018 NPRM, we stated that ''while we believe the industry commenters' suggestion of multiplying the aggregate daily wage by 200, rather than 270, has merit, we have decided that in the interests of recruiting and retaining a suitable number of experienced pilots, a multiplier of 270 is the preferable course of action. The Coast Guard also noted ''[w]hile we have considered the argument that it would be more efficient to pay pilots less or have fewer of them to generate lower shipping rates, we believe the effect on safety and reliability warrant a multiplier of 270.'' [48] With regard to the additional overtime figure, we adopted it because the commenter who provided the overtime figures had firsthand knowledge of the contract between the AMO and the shippers.[49] If the commenter has information about this contract that could be shared which would cause the Coast Guard to question the validity of the overtime figure, we would be open to receiving it. However, as no additional information has been supplied, we will continue to use the best information we have to calculate the target compensation, which at this time includes the overtime figure.

b. Comparisons With Other U.S. Pilots

One commenter argued that ''the proposed 2019 target compensation also continues to lag [behind] the compensation of other U.S. pilots by a considerable margin.'' The commenter went on to argue that ''the pilots stand ready to assist the Coast Guard in [studying pilot compensation]'' and ''urge the Coast Guard to review the information they [the pilots] have provided, which they believe supports a higher compensation level.'' [50] The Coast Guard notes that the past information provided by the pilot associations contains recent total compensation information for selected pilot groups in other regions. However, because target compensation and actual compensation are quite different (in recent years, actual compensation has been significantly higher than target compensation due to higher-than-expected shipping demand), we cannot directly compare the two. We would welcome submission of actual pilot compensation data for Great Lakes pilots in recent years to improve our analysis, and will raise it as an issue in a future Great Lakes Pilotage Advisory Committee meeting.

E. Manning and Traffic Figures

a. Manning

Several commenters raised issues relating to the calculation of the number of pilots needed, given anticipated traffic on the Great Lakes (the staffing model). In the 2019 NPRM, using that model, we left the maximum number of pilots at 54 total, although for 2019 we proposed authorizing only 51 pilots, an increase of two pilots over the authorized number for 2018. Based on the comments received, the Coast Guard is not making changes to the staffing model at this time, but note the concerns of the commenters, as discussed below.

One commenter argued that ''with the growth of tanker and cruise ship traffic, vessel transit frequency no longer subsides during the summer period. The result is pilots being unable to realize the restorative rest stated as a goal in the manning models and needed for continued safe operation.'' [51] The Coast Guard believes this is potentially a valid point. The current staffing model is based on the historic increased need for pilots at the start and close of the season, and that by staffing to meet that need, it allows pilots to take approximately 10 days of restorative rest each month during the seven-month mid-season period. We are currently monitoring traffic patterns, and if the commenter's assertion proves accurate, it would cause us to reevaluate the staffing model. While at this time we are still gathering data, we would appreciate additional data and suggestions for alternative staffing models in light of changes in traffic patterns.

Another commenter criticized the Coast Guard's use of rounding up the number of pilots authorized to operate in a district as a means of calculating the administrative time required of each association's president.[52] The commenter suggests that the Coast Guard ''devise a better method'' to account for the president's administrative duties. We disagree with the commenter's suggestion. We note that, because we are calculating the number of full-time pilots, we must round to the nearest whole number in any event. Furthermore, because administrative time varies widely, it is difficult to assign a concrete number to that duty. We continue to believe that upward rounding of the number of pilots needed is appropriate given that the association president is both a pilot providing service and the lead administrator for the association. We, however, encourage the commenter to suggest an alternative method for calculating administrative time.

b. Use of Bridge Hours and Average Traffic Figures

One commenter raised questions about the validity and consistency of various calculations used in the Coast Guard's ratemaking methodology. Specifically, the commenter stated that the ''use of inconsistent time periods for varying data sets—*e.g.,* a ten-year rolling average of historical traffic volume data against three-year or one-year data for determining expense levels or pilot staffing needs'' [53] was a pressing concern. We believe that the commenter has mischaracterized the Coast Guard's data collection and aggregation efforts, and we will attempt to explain them here.

The first issue is the use of the historical traffic average (sometimes referred to as ''actual traffic'') to determine anticipated traffic volumes, which we implement by using a rolling 10-year average. The Coast Guard requires an estimate of the amount of traffic in the upcoming year as part of its ratemaking methodology as this is not something that can be measured beforehand. To derive this estimate, the

[46] USCG–2018–0665–0010, p. 4.

[47] USCG–2018–0665–0010, p. 5.

[48] 83 FR 26171.

[49] 83 FR 26169.

[50] USCG–2018–0665–0008, p. 3.

[51] USCG–2018–0665–0009, p. 2.

[52] USCG–2018–0665–0006, p. 5.

[53] USCG–2018–0665–0010, p. 2.

Coast Guard takes the average of the previous 10 years of traffic in each area on the Great Lakes. The use of the historical traffic figure was unanimously recommended by the Great Lakes Pilotage Advisory Committee (GLPAC) in 2014,[54] and we believe that it is the best tool we have to estimate traffic. While in recent years high levels of traffic have been greater than the historical average, we also note that, not unexpectedly, in some years, the level of traffic has been lower than average. The use of the 10-year average may cause the average to lag trends, but it does reduce fluctuations in predicted traffic levels resulting in a more stable rate on a year to year basis. While we are open to suggestions as to how to better predict total traffic, we would encourage the commenters to raise these suggestions at the GLPAC, as we are currently continuing to follow its recommendation on this subject.

Unlike the traffic prediction, the other factors the commenters cite (the operating expenses and number of authorized pilots) are measured numbers, and thus do not require a predictive mechanism. The operating expenses (the ''three-year'' figure) are direct reimbursements for actual expenses three years previous. The reason for the delay is the time it takes to receive, audit, and present those numbers through the rulemaking process. Similarly, the Director of Great Lakes Pilotage determines the number of working pilots (the ''one-year'' figure) based on measured training progressions and retirement announcements. These are not predictions that would require us to average a previous year's estimates or use some other mechanism to make predictions. For these reasons, the Coast Guard does not believe the commenter's concern regarding the different time periods at issue represents a flaw in the Coast Guard's ratemaking methodology.

c. Calculation of 2017 Traffic Figure for District 3

One commenter suggested that the Coast Guard had made an error in its calculation of the total traffic figures for District 3. The commenter stated that the Coast Guard's 2017 total traffic figures (26,183 hours in undesignated waters and 3,798 hours in designated waters) were inaccurate, and that the correct figures for that year were 20,955 hours in undesignated waters, and 2,997 hours in designated waters.[55] In response to this comment, we reviewed the data from 2017 and were unable to replicate the traffic figures cited in the NPRM. We were, however, able to validate the commenter's figures using the search parameters they provided. For that reason, we believe that the information provided by the commenter provides a stronger basis for the 2017 traffic figures, and have made the adjustment accordingly.

F. Working Capital Fund

In the NPRM, the Coast Guard requested comments on the utility and value of the working capital fund and in response, received several comments and questions regarding its origins, uses, and tax implications. One commenter stated that while it appreciated that the working capital fund provides a revenue stream intended to be used for infrastructure, one problem is that the Coast Guard ''hasn't established any guidelines or limits on acceptable uses.'' [56] Another commenter suggested changes to the way the working capital fund operates. Currently, the working capital fund ''is structured so that the pilot associations can demonstrate credit worthiness when seeking funds from a financial institution for needed infrastructure projects, and those projects can produce a return on investment at a rate commensurate to repay a financial institution.'' [57] The commenter argued that ''if the reserve fund is used for improvements then it is not available to provide a return on investment,'' [58] and recommended that the interest rate on which the value of the working capital fund is calculated be dramatically increased (the commenter suggested London Interbank Offered Rate (LIBOR) + 4 percent). We disagree with this suggestion, and believe the commenter has misinterpreted the Coast Guard's intent. In previous years, the goal of the ''return on investment'' step, the precursor of the working capital fund, was to provide a return to monies invested by the pilots in associations. The amount of the money invested (the investment base) by pilots was relatively small, and thus the return on that investment was small in absolute terms. However, when we recalibrated the return on investment (later dubbed the working capital fund) to be based on the total income of the associations, rather than simply the money invested in capital improvements, the goal was to increase infrastructure spending by providing a more substantial pool of available funds.

The goal of the working capital fund is not to provide a windfall for the associations. It is to demonstrate that associations can accrue additional capital, and thus have the resources to invest in infrastructure, either with the capital on hand or by financing a loan. It is not designed to provide extra money for associations to distribute to their shareholders.

Industry commenters had a very negative view of the working capital fund. In addition to several concerns about the terminology, the commenter stated that ''the Coast Guard does not impose safeguards to require segregation of funds generated as a result of this element'' or ''ensure that such funds are used in a manner consistent with Coast Guard explanations as to why the [working capital fund] exists.'' [59] The commenter argued that ''there has been no indication as to why a ''Working Capital'' figure would be the product or function of multiplying the sum of operating expenses and target pilot compensation by [AAA bond yields].'' Finally, industry commenters asserted that ''until the Coast Guard establishes exactly what this component of the pilotage revenue stream is, how it should be rationally computed, and how it must be used, the correct value of the [working capital fund] should be set at $0.'' [60]

Based on comments received, it is clear that both pilots and industry are in favor of clear guidelines for the working capital fund. To this end, the Coast Guard transmitted a letter to the pilot associations, dated November 30, 2018 and now available in the docket,[61] to establish the uses and restrictions on the working capital fund. To summarize, 46 U.S.C. 9304 and 46 CFR 401.320 authorize the Coast Guard to outline how each respective pilotage association will manage the funds generated by the Working Capital Fund until the Coast Guard can update regulations or policy concerning the Working Capital Fund. The Coast Guard's November 30 letter therefore requires that pilot associations segregate the revenues generated by the working capital fund step, and provide a report on the status of these funds annually.[62] The funds are to be used for

[54] See Great Lakes Pilotage Advisory Committee meeting transcript, July 23, 2014, at p. 254 to 258.

[55] USCG–2018–0665–0006, p. 2.

[56] USCG–2018–0665–0006, p. 6.

[57] 83 FR 26173, citing 82 FR 41466, p. 41484.

[58] USCG–2018–0665–0008, p. 4.

[59] USCG–2018–0665–0010, p.7.

[60] USCG–2018–0665–0010, p.7.

[61] USCG–2018–0665–0011.

[62] We note that in the letter we stated that there would be an auditing report required on April 7 each year, and at this time the Information Collection Request (ICR) for the Great Lakes Pilotage Ratemaking does not currently cover this information request. The Coast Guard will amend the current ICR to include this information, however until the Office of Information and

Continued

capital expenditures only, and are subject to a reasonableness standard. We believe that this letter will help to ensure that working capital fund revenues are used for their intended purposes of facilitating infrastructure improvements.

G. Use of the Martin Report

The Coast Guard received one comment on the use of the 2017 Martin Associates report, ''Analysis of Great Lakes Pilotage Costs on Great Lakes Shipping and the Potential Impact of Increases in U.S. Pilotage Charges,'' in our regulatory analysis.[63] The commenter believes the study should not be used for any part of the rulemaking process because the study is biased toward industry, relies upon faulty invoice data, and uses a flawed methodology to estimate the impact of increasing pilotage rates on vessel traffic and employment in the Great Lakes. According to the commenter, these alleged faults in the Martin Report would overestimate the impact on pilotage rates on shipping. The commenter did not, however, object to using the Martin Report to support the proposition that the proposed 2019 pilotage rate increases would not ''have significant secondary economic harms.'' Given the commenter's conclusion, the Coast Guard will not address the commenter's concerns here. Nevertheless, the regulatory analysis of this final rule does not rely upon the Martin Report because the data used in that report is now several years old and out-of-date to support our analysis.

One commenter contested the Coast Guard's use of an upper rate standard, as elucidated in the Martin Report, to determine that the rates are set ''giving consideration to the public interest'' in accordance with the Great Lakes Pilotage Act. Referencing the Coast Guard's response to the commenter in the 2018 Annual Review, that commenter argued that ''an upper rate standard based on 'levels that threaten the economic viability of Great Lakes Shipping' is not a useful or responsible standard.'' [64] The commenter went on to state that rate increases are resulting ''in negative economic impacts on ports, agents, other maritime community stakeholders, and the economic well-being of the region'' without providing support for that position. While the commenter suggested that data on actual pilot compensation would assist the Coast Guard in developing an alternative method of meeting its statutory obligation to give consideration to the public interest, it was neither clear what that alternative measure would be nor how pilot compensation data would affect in development of that alternative. Given the absence of alternative methods, we consider the use of the Martin Report's estimates on the possible economic impact to be one tool to gauge the impact of pilotage rates on shipping. Finally, impact on shipping is not the only consideration for the Coast Guard in determining the public interest. The protection of the marine environment from oil spills resulting from groundings and collisions and the protection of maritime infrastructure, *e.g.,* locks, are also in the public interest. Professional pilotage services provided for under this ratemaking reduce the risks of such an incident occurring and increases the safety of maritime traffic on the Great Lakes. Consequently, the Coast Guard considers the safety of maritime traffic on the Great Lakes to be in the public interest.

H. Other Issues Concerning Ratemaking Procedures

a. Over-Realization of Pilotage Revenue

One commenter raised the issue that actual revenue realizations in the years 2014–2017 exceeded the target revenues by a considerable amount. As an example, the commenter noted that, in 2017, $26.5 million in pilotage revenue was realized, which was far in excess of the stated target of $21.7 million.[65] The commenter requested that the Coast Guard ''validate the real world likelihood of additional over-realization by using known information on pilotage billings to date for 2018 to assess whether rate increases . . . are, in fact necessary to achieve revenue targets stated in the Proposed Rule.'' [66]

While the Coast Guard agrees with the commenter that, in several recent years, realized revenues have exceeded target revenues, we do not believe this is a systemic or perpetual position. We note that, as rates are derived by using an average of the most recent 10 years of traffic, if the traffic in the current year exceeds the average (*i.e.,* it is a busier than an average year), pilots will realize more than the target revenue, and if it is a slower than an average year, pilots will realize less than the target revenue. Because the last several years that the commenters cite have seen larger-than-average traffic flows, additional revenue has been realized.[67] We also believe that it is important to clarify that meeting the ''target revenue'' is not a goal for the Coast Guard in and of itself; the target revenue is just a marker used by the ratemaking methodology to set rates assuming an average traffic year. The revenue realized is expected to vary from ''target revenue'' consistent with the manner actual traffic varies from the projected traffic.

The Coast Guard does agree with the commenter that known information on 2018 traffic should be incorporated into the 2019 ratemaking calculation. The calculations in this final rule are based on traffic in a 10-year period of 2009–2018. We note that generally the most recent year's traffic figures are not included in the NPRM, which comes out before the end of the previous year's season, but are included in the final rule of the annual ratemaking.

The commenter also urged the Coast Guard to ''require Pilot Association financials to provide individual pilot compensation data, screened to protect individual pilot identities, as part of the standard annual financial reports.'' [68] The commenter suggests that this information is ''critical in evaluating frequent, but vague and non-empirical justifications based on recruitment, retention, and attrition of pilots proffered by the Coast Guard to [increase pilot compensation].'' [69] While, as stated above, the Coast Guard believes this information could be used to more accurately compare the compensation of Great Lakes pilots to known salaries of pilots in other pilot associations, we would need more specific suggestions on how this information would be incorporated into the ratemaking methodology before considering requiring it.

b. Disparity of Rates Between U.S. and Canadian Pilotage

One commenter raised questions about the difference between U.S. and Canadian pilotage cost structures. The commenter stated that ''sample comparisons of the costs of U.S. versus Canadian pilotage on the same or similar voyages by the same or similar vessels show that U.S. pilotage costs are often nearly twice as high as those of the

Regulatory Affairs (OIRA) approves this ICR amendment, we will not enforce this collection.

[63] The study is available at *http://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Marine-Transportation-Systems-CG-5PW/Office-of-Waterways-and-Ocean-Policy/Office-of-Waterways-and-Ocean-Policy-Great-Lakes-Pilotage-Div/.*

[64] USCG–2018–0665–0010, p.3.

[65] USCG–2018–0665–0010, p.5.

[66] USCG–2018–0665–0010, p.6.

[67] We also note that the commenters may be including revenue from non-compulsory pilotage in their realized revenue calculations. We note that the current methodology does count revenue from this source in developing the target revenue.

[68] USCG–2018–0665–0010, p.6.

[69] USCG–2018–0665–0010, p.6.

Canadian counterparts.'' [70] The commenter cites a CPCS report, which contains an example where a vessel was billed $21,054 for an American pilot and $6,431 for a Canadian pilot, while the two pilots were simultaneously deployed in a double-pilotage situation.[71] The commenter asked why the rates were so different, and what justified the difference in rates.

The Coast Guard is aware that the U.S. and Canada do not bill for service in identical ways. One significant difference between the U.S. and Canada is that the U.S. has three different Districts that must each support themselves, whereas the Canadian GLPA operates as a unified whole. This means that there may be a level of cross-subsidization among Canadian pilots that is impossible to replicate on the American side, which could result in higher rates in some areas (and lower rates in others).[72] Simple anecdotal comparisons on a single voyage do not provide the Coast Guard with the comprehensive information needed to determine if there is a system-wide problem with rates or if we are merely seeing a rare, if extreme, incident.

I. Out-of-Scope Issues

Industry commenters provided several comments that are not directly pertinent to this ratemaking action. These included comments on pilotage charges assessed early and late in the navigation season, where charges may accrue while a vessel is not under active navigation. Industry commenters also requested development of a mechanism for an alternative provision of pilotage services, as well as a mechanism by which money collected in previous years under a system found to be arbitrary by a court could be refunded, such as through a ''negative surcharge'' or other means. Comments also addressed various issues relating to labor disputes, disputed instances where a tug is requested by a pilot, and issues regarding delays caused by various factors outside a ship's control.

The Coast Guard is not addressing these comments in this document, as they are out of the scope of the ratemaking action. We note that this regulation is narrowly confined to the actual hourly rates charged in 2019 and the data and calculations used to develop those rates. If industry commenters wish to address these concerns in a separate process, they are encouraged to reach out by formal or informal means to the Great Lakes Pilotage Office or submit a petition for rulemaking laying out specific changes to the program they would like to see and include supporting data.

J. Changes Resulting From Litigation

On February 19, 2019, the United States Court for the District of Columbia issued an opinion in St. Lawrence Seaway Pilots Association *et al.* v. United States Coast Guard.[73] The District Court held that paragraph (b)(6) of 33 CFR 404.2, which states that legal fees incurred in litigation against the Coast Guard cannot be recouped as operating expenses, had been improperly promulgated, and vacated the provision. In this final rule we are removing that paragraph from section 404.2. While we did not propose removing this text in the NPRM, because the text has been vacated by judicial order after publication of the NPRM, under 5 U.S.C. 553(b)(B), notice and comment is unnecessary.

VI. Discussion of Current Rate Adjustments

In this final rule, based on the current methodology described in the previous section, the Coast Guard is establishing new pilotage rates for 2019. This section discusses the rate changes using the ratemaking steps provided in 46 CFR part 404. We will detail each step of the ratemaking procedure to show how we arrived at the established new rates.

We conducted the 2019 ratemaking as an ''interim year,'' rather than a full ratemaking. Thus, for this purpose, the Coast Guard will adjust the compensation benchmark pursuant to § 404.104(b) rather than § 404.104(a).

A. Step 1: Recognize Previous Operating Expenses

Step 1 in our ratemaking methodology requires that the Coast Guard review and recognize the previous year's operating expenses (§ 404.101). To do so, we begin by reviewing the independent accountant's financial reports for each association's 2016 expenses and revenues.[74] For accounting purposes, the financial reports divide expenses into designated and undesignated areas. In certain instances, for example, costs are applied to the undesignated or designated area based on where they were actually accrued. For example, costs for ''Applicant pilot license insurance'' in District One are assigned entirely to the undesignated areas, as applicant pilots work exclusively in those areas. For costs that are accrued to the pilot associations generally, for example, pilot insurance, the cost is divided between the designated and undesignated areas on a *pro rata* basis. The recognized operating expenses for the three districts are laid out in tables 3 through 5.

As noted above, in 2016, the Coast Guard began authorizing surcharges to cover the training costs of applicant pilots. The surcharges were intended to reimburse pilot associations for training applicants in a more timely fashion than if those costs were listed as operating expenses, which would have required three years to reimburse. The rationale for using surcharges to cover these expenses, rather than including the costs as operating expenses, was so that retiring pilots would not have to cover the costs of training their replacements. Because operating expenses incurred are not actually recouped for a period of three years, beginning in 2016, the Coast Guard added a $150,000 surcharge per applicant pilot to recoup those costs in the year incurred. To ensure that the ratepayers are not double-billed for the same expense(s), we deduct the amount collected via surcharges from the operating expenses. For that reason, the Coast Guard has established a ''surcharge adjustment from 2016'' as part of its adjustment for each pilotage district. This surcharge adjustment reflects the additional monies that were collected by the surcharge that year. We note that in 2016, there was no mechanism to prevent the collection of surcharges above the authorized amounts, and so the amounts we deducted from each association's operating expenses are equal to the actual amount of surcharges collected in the 2016 shipping season, which are in excess of $150,000 per applicant pilot.

The Coast Guard also deducted 3 percent of the ''shared counsel'' expenses for each district, to account for lobbying expenditures, which we do not consider ''reasonable and necessary'' to conduct operations (with the exception of District 3, for reasons described in the ''Operating Expenses'' section above).

For each of the analyses of the operating expenses below, we explained in the NPRM why we established the Director's adjustments, other than the surcharge adjustments and lobbying expenses, described above. Other adjustments were made by the auditors and are explained in the auditor's reports, which are available in the docket for this rulemaking. Numbers by the entries are references to descriptions in the auditor's reports. Finally, we note

[70] USCG–2018–0665–0010, p.3.

[71] USCG–2018–0665–0010, exhibit 3, p.8.

[72] The inability to replicate the possible sharing of costs across the entire Canadian system is exacerbated by the fact that only Canadian pilots provide pilotage services in Area 3.

[73] 357 F. Supp. 3d 30.

[74] These reports are available in the docket for this rulemaking (see Docket #USCG–2018–0665).

that several changes to the NPRM's proposed operating expenses have been made as a result of the notice and comment process—described above in the ''Operating Costs'' portion of Section V.

TABLE 3—2016 RECOGNIZED EXPENSES FOR DISTRICT ONE

District One	Designated	Undesignated	Total
Reported Expenses for 2016	St. Lawrence River	Lake Ontario	
Costs Relating to Pilots:			
Pilot subsistence/travel	$421,749	$336,384	$758,133
Subsistence/Travel—Pilots (D1–16–01)	−70,224	−34,846	−105,070
License insurance	40,464	28,269	68,733
Payroll taxes	111,279	90,179	201,458
Payroll taxes—Pilots (D1–16–03)	0	−2,509	−2,509
Training	17,198	13,717	30,915
Training—Pilots (D1–16–04)	−594	0	−594
Other	842	672	1,514
Total costs relating to pilots	520,714	431,866	952,580
Applicant Pilots:			
Wages	70,700	90,000	160,700
Wages (D1–16–02)	0	28,054	28,054
Subsistence/Travel	0	146,219	146,219
Subsistence/Travel—Trainees (D1–16–02)	−12,283	−20,589	−32,872
Benefits	0	0	0
Payroll taxes	8,039	11,123	19,162
Payroll taxes—Trainees (D1–16–03)	0	−5,115	−5,115
Surcharge Offset—Director's Adjustment	−318,117	−253,649	−571,766
Total applicant pilot costs	−251,661	−3,957	−255,618
Pilot Boat and Dispatch Costs:			
Pilot boat expense	209,800	167,335	377,135
Dispatch expense	51,240	31,705	82,945
Payroll taxes	16,007	12,767	28,774
Total pilot and dispatch costs	277,047	211,807	488,854
Administrative Expenses:			
Legal—general counsel	4,565	3,641	8,206
Legal—shared (K&L Gates) (D1–16–05)	20,558	16,397	36,955
Legal—shared (K&L Gates) (D1–16–05)	−713	−713	−1,426
Legal—shared counsel 3% lobbying fee (K&L Gates) (Director's Adjustment)	−617	−492	−1,109
Office rent	0	0	0
Insurance	21,869	17,443	39,312
Employee benefits—Admin	9,428	7,519	16,947
Payroll taxes—Admin	6,503	5,187	11,690
Other taxes	274,503	218,941	493,444
Admin Travel	2,346	1,871	4,217
Depreciation/Auto leasing/Other	65,971	52,618	118,589
Interest	20,688	16,501	37,189
Dues and Subscriptions (incl. APA) (D1–16–05)	29,687	13,959	43,646
Dues and Subscriptions (incl. APA) (D1–16–05)	−1,079	−1,079	−2,158
Utilities	12,318	9,578	21,896
Salaries—Admin	65,401	52,163	117,564
Accounting/Professional fees	5,479	3,921	9,400
Other	23,456	18,708	42,164
Total Administrative Expenses	560,363	436,163	996,526
Capital Expenditures:			
Property Acquisition (Directors Adjustment)	280,164	186,776	466,940
Total Operating Expenses	1,386,627	1,262,655	2,649,282

TABLE 4—2016 RECOGNIZED EXPENSES FOR DISTRICT TWO

District Two	Undesignated	Designated	Total
Reported expenses for 2016	Lake Erie	SES to Port Huron	
Pilot-related expenses:			
Pilot subsistence/travel	$131,956	$197,935	$329,891
Pilot subsistence/travel CPA Adjustment (D2–16–01)	−44,955	−67,433	−112,388
License insurance	10,095	15,142	25,237
License Insurance CPA Adjustment (D2–16–03)	−635	−953	−1,588

TABLE 4—2016 RECOGNIZED EXPENSES FOR DISTRICT TWO—Continued

District Two	Undesignated	Designated	Total
Reported expenses for 2016	Lake Erie	SES to Port Huron	
Payroll taxes	77,306	115,958	193,264
Total Pilot-related expenses	173,767	260,649	434,416
Expenses related to applicant pilots:			
Wages (from supplemental form)	228,499	342,749	571,248
Wages—Director's Adjustment	−125,472	−188,209	−313,681
Benefits (from supplemental form)	9,736	14,605	24,341
Benefits—Director's Adjustment	60,031	0	60,031
Applicant pilot Subsistence/Travel	43,905	65,858	109,763
Applicant Pilot subsistence/travel CPA Adjustment (D2–16–02)	−14,940	−22,410	−37,350
Housing Allowance CPA Adjustment (D2–16–02)	14,940	22,410	37,350
Payroll taxes	15,144	22,717	37,861
2016 Surcharge Offset Director's Adjustment	−158,640	−277,106	−435,746
Total applicant pilot expenses	73,203	−19,386	53,817
Pilot Boat and Dispatch Costs:			
Pilot boat expense	205,572	308,359	513,931
Dispatch expense	8,520	12,780	21,300
Employee benefits	75,405	113,107	188,512
Payroll taxes	10,305	15,457	25,762
Total pilot and dispatch costs	299,802	449,703	749,505
Administrative Expenses:			
Office rent	26,275	39,413	65,688
Office Rent CPA Adjustment	4,766	7,150	11,916
Legal—general counsel	1,624	2,437	4,061
Legal—shared counsel (K&L Gates)	13,150	19,725	32,875
Legal—shared counsel CPA Adjustment	−526	−789	−1,315
Legal—shared counsel 3% lobbying fee (K&L Gates) (Director's Adjustment)	−395	−592	−987
Employee Benefits—Admin Employees	59,907	89,861	149,768
Employee benefits (Director's Adjustment)	−30,200	−60,400	−90,600
Workman's compensation—pilots	74,561	111,841	186,402
Payroll taxes—admin employees	5,688	8,532	14,220
Insurance	10,352	15,529	25,881
Other taxes	9,149	13,723	22,872
Administrative Travel	18,205	27,307	45,512
Administrative Travel (D2–16–06)	−153	−229	−382
Depreciation/auto leasing/other	39,493	59,239	98,732
Depreciation/Auto leasing/Other CPA Adjustment (D2–16–03)	−221	−332	−553
Interest	6,224	9,336	15,560
APA Dues	17,145	25,717	42,862
APA Dues CPA Adjustment (D2–16–04)	−815	−1,223	−2,038
Utilities	16,748	25,121	41,869
Salaries	55,426	83,139	138,565
Accounting/Professional fees	12,520	18,780	31,300
Other	128,093	192,139	320,232
Other CPA Adjustment (D2–16–07)	−221	−332	−553
Total Administrative Expenses	466,795	685,092	1,151,887
Total Operating Expenses	1,013,567	1,376,058	2,389,625

TABLE 5—2016 RECOGNIZED EXPENSES FOR DISTRICT THREE

District Three	Undesignated	Designated	Total
Reported Expenses for 2016	Lakes Huron and Michigan and Lake Superior	St. Mary's River	
Pilotage Costs:			
Pilot subsistence/travel	$378,014	$100,485	$478,499
Pilot subsistence/Travel (D3–16–01)	−50,285	−13,367	−63,652
Pilot subsistence/Travel director's adjustment (housing allowance)	0	−36,900	−36,900
License insurance	21,446	5,701	27,147
Payroll taxes	194,159	51,612	245,771
Other	19,193	72,202	91,395

TABLE 5—2016 RECOGNIZED EXPENSES FOR DISTRICT THREE—Continued

District Three	Undesignated	Designated	Total
Reported Expenses for 2016	Lakes Huron and Michigan and Lake Superior	St. Mary's River	
Total Pilotage Costs	562,527	179,733	742,260
Applicant Pilots:			
Wages	610,433	162,267	772,700
Benefits	160,265	26,644	186,909
Subsistence/travel	170,089	45,214	215,303
Payroll taxes	50,561	13,440	64,001
Training	11,642	3,095	14,737
Surcharge Adjustment	−1,106,339	−235,673	−1,342,012
Total applicant pilotage costs	−103,349	14,987	−88,362
Pilot Boat and Dispatch Costs:			
Pilot boat costs	580,822	154,396	735,218
Pilot boat costs (D3–16–02)	−72,724	−19,332	−92,056
Dispatch costs	146,220	38,868	185,088
Employee benefits	6,517	1,733	8,250
Payroll taxes	15,745	4,186	19,931
Total pilot boat and dispatch costs	676,580	179,851	856,431
Administrative Expenses:			
Legal—general counsel	22,196	5,900	28,096
Legal—shared counsel (K&L Gates)	34,020	9,043	43,063
Office rent	6,978	1,855	8,833
Insurance	14,562	3,871	18,433
Employee benefits	103,322	27,465	130,787
Payroll Taxes (administrative employees)	6,540	1,739	8,279
Other taxes	1,338	356	1,694
Depreciation/auto leasing/other	46,016	12,232	58,248
Interest	2,775	738	3,513
APA Dues	24,760	6,582	31,342
Utilities	38,763	10,304	49,067
Administrative Salaries	94,371	25,086	119,457
Accounting/Professional fees	31,877	8,474	40,351
Pilot Training	35,516	9,441	44,957
Other	13,619	3,621	17,240
Other expenses (D3–16–03)	−$2,054	−$546	−$2,600
Total Administrative Expenses	474,599	126,161	600,760
Total Operating Expenses	1,610,357	500,732	2,111,089

B. Step 2: Project Operating Expenses, Adjusting for Inflation or Deflation

Having identified the recognized 2016 operating expenses in Step 1, the next step is to estimate the current year's operating expenses by adjusting those expenses for inflation over the 3-year period. The Coast Guard calculated inflation using the BLS data from the CPI for the Midwest Region of the United States [75] and reports from the Federal Reserve.[76] Based on that information, the calculations for Step 1 are as follows:

TABLE 6—ADJUSTED OPERATING EXPENSES FOR DISTRICT ONE

	Designated	Undesignated	Total
Total Operating Expenses (Step 1)	$1,386,627	$1,262,655	$2,649,282
2017 Inflation Modification (@1.7%)	23,573	21,465	45,038
2018 Inflation Modification (@1.9%)	26,794	24,398	51,192
2019 Inflation Modification (@2.1%)	30,177	27,479	57,656
Adjusted 2019 Operating Expenses	1,467,171	1,335,997	2,803,168

[75] Available at *https://www.bls.gov/regions/midwest/data/consumerpriceindexhistorical_midwest_table.pdf*. Specifically the Consumer Price Index is defined as ''All Urban Consumers (CPI–U), All Items, 1982 – 4 = 100''. Downloaded January 31, 2019.

[76] Available at *https://www.federalreserve.gov/monetarypolicy/files/fomcprojtabl20180613.pdf*. We used the PCE median inflation value found in Table 1, Downloaded January 31, 2019.

TABLE 7—ADJUSTED OPERATING EXPENSES FOR DISTRICT TWO

	Undesignated	Designated	Total
Total Operating Expenses (Step 1)	$1,013,567	$1,376,058	$2,389,625
2017 Inflation Modification (@1.7%)	17,231	23,393	40,624
2018 Inflation Modification (@1.9%)	19,585	26,590	46,175
2019 Inflation Modification (@2.1%)	22,058	29,947	52,005
Adjusted 2019 Operating Expenses	1,072,441	1,455,988	2,528,429

TABLE 8—ADJUSTED OPERATING EXPENSES FOR DISTRICT THREE

	Undesignated	Designated	Total
Total Operating Expenses (Step 1)	$1,610,357	$500,732	$2,111,089
2017 Inflation Modification (@1.7%)	27,376	8,512	35,888
2018 Inflation Modification (@1.9%)	31,117	9,676	40,793
2019 Inflation Modification (@2.1%)	35,046	10,897	45,943
Adjusted 2019 Operating Expenses	1,703,896	529,817	2,233,713

C. Step 3: Estimate Number of Working Pilots

In accordance with the text in § 404.103, we estimated the number of working pilots in each district. Based on input from the Saint Lawrence Seaway Pilots Association, we estimate that there will be 17 working pilots in 2019 in District One. Based on input from the Lakes Pilots Association, we estimate there will be 14 working pilots in 2019 in District Two. Based on input from the Western Great Lakes Pilots Association, we estimate there will be 20 working pilots in 2019 in District Three.

Furthermore, based on the staffing model employed to develop the total number of pilots needed, we assign a certain number of pilots to designated waters and a certain number to undesignated waters. These numbers are used to determine the amount of revenue needed in their respective areas.

TABLE 9—AUTHORIZED PILOTS

	District One	District Two	District Three
Maximum number of pilots (per § 401.220(a)) [77]	17	15	22
2019 Authorized pilots (total)	17	14	20
Pilots assigned to designated areas	10	7	4
Pilots assigned to undesignated areas	7	7	16

D. Step 4: Determine Target Pilot Compensation Benchmark

In this step, we determine the total pilot compensation for each area. Because this is an ''interim'' ratemaking this year, we follow the procedure outlined in paragraph (b) of § 404.104, which adjusts the existing compensation benchmark by inflation. Because we do not have a value for the employment cost index for 2019, we multiply last year's compensation benchmark by the Median PCE Inflation of 2.1 percent.[78] Based on the projected 2019 inflation estimate, the compensation benchmark for 2019 is $359,887 per pilot.

Next, we certify that the number of pilots estimated for 2019 is less than or equal to the number permitted under the staffing model in § 401.220(a). The staffing model suggests that the number of pilots needed is 17 pilots for District One, 15 pilots for District Two, and 22 pilots for District Three,[79] which is more than or equal to the numbers of working pilots provided by the pilot associations.

Thus, in accordance with § 404.104(c), we use the revised target individual compensation level to derive the total pilot compensation by multiplying the individual target compensation by the estimated number of working pilots for each district, as shown in tables 10–12.

TABLE 10—TARGET COMPENSATION FOR DISTRICT ONE

	Designated	Undesignated	Total
Target Pilot Compensation	$359,887	$359,887	$359,887
Number of Pilots	10	7	17
Total Target Pilot Compensation	$3,598,870	$2,519,209	$6,118,079

[77] For a detailed calculation of the staffing model, see 82 FR 41466, table 6 on p. 41480 (August 31, 2017).

[78] *https://www.federalreserve.gov/monetarypolicy/files/fomcprojtabl20180613.pdf.*

[79] See Table 6 of the 2017 final rule, 82 FR 41466 at 41480 (August 31, 2017). The methodology of the staffing model is discussed at length in the final rule (see pages 41476–41480 for a detailed analysis of the calculations).

TABLE 11—TARGET COMPENSATION FOR DISTRICT TWO

	Undesignated	Designated	Total
Target Pilot Compensation	$359,887	$359,887	$359,887
Number of Pilots	7	7	14
Total Target Pilot Compensation	$2,519,209	$2,519,209	$5,038,418

TABLE 12—TARGET COMPENSATION FOR DISTRICT THREE

	Undesignated	Designated	Total
Target Pilot Compensation	$359,887	$359,887	$359,887
Number of Pilots	16	4	20
Total Target Pilot Compensation	$5,758,192	$1,439,548	$7,197,740

E. Step 5: Project Working Capital Fund

Next, we calculate the working capital fund revenues needed for each area. First, we add the figures for projected operating expenses and total pilot compensation for each area. Next, we find the preceding year's average annual rate of return for new issues of high grade corporate securities. Using Moody's data, that number is 3.93 percent.[80] By multiplying the two figures, we get the working capital fund contribution for each area, as shown in tables 13–15.

TABLE 13—WORKING CAPITAL FUND CALCULATION FOR DISTRICT ONE

	Designated	Undesignated	Total
Adjusted Operating Expenses (Step 2)	$1,467,171	$1,335,997	$2,803,168
Total Target Pilot Compensation (Step 4)	3,598,870	2,519,209	6,118,079
Total 2019 Expenses	5,066,041	3,855,206	8,921,247
Working Capital Fund (3.93%)	199,095	151,510	350,605

TABLE 14—WORKING CAPITAL FUND CALCULATION FOR DISTRICT TWO

	Undesignated	Designated	Total
Adjusted Operating Expenses (Step 2)	$1,072,441	$1,455,988	$2,528,429
Total Target Pilot Compensation (Step 4)	2,519,209	2,519,209	5,038,418
Total 2019 Expenses	3,591,650	3,975,197	7,566,847
Working Capital Fund (3.93%)	141,152	156,225	297,377

TABLE 15—WORKING CAPITAL FUND CALCULATION FOR DISTRICT THREE

	Undesignated	Designated	Total
Adjusted Operating Expenses (Step 2)	$1,703,896	$529,817	$2,233,713
Total Target Pilot Compensation (Step 4)	5,758,192	1,439,548	7,197,740
Total 2019 Expenses	7,462,088	1,969,365	9,431,453
Working Capital Fund (3.93%)	293,260	77,396	370,656

F. Step 6: Project Needed Revenue

In this step, we add up all the expenses accrued to derive the total revenue needed for each area. These expenses include the projected operating expenses (from Step 2), the total pilot compensation (from Step 4), and the working capital fund contribution (from Step 5). The calculations are shown in tables 16 through 18.

[80] Moody's Seasoned Aaa Corporate Bond Yield, average of 2018 monthly data. The Coast Guard uses the most recent complete year of data. See *https://fred.stlouisfed.org/series/AAA*. (February 14, 2019)

TABLE 16—REVENUE NEEDED FOR DISTRICT ONE

	Designated	Undesignated	Total
Adjusted Operating Expenses (Step 2)	$1,467,171	$1,335,997	$2,803,168
Total Target Pilot Compensation (Step 4)	3,598,870	2,519,209	6,118,079
Working Capital Fund (Step 5)	199,095	151,510	350,605
Total Revenue Needed	5,265,136	4,006,716	9,271,852

TABLE 17—REVENUE NEEDED FOR DISTRICT TWO

	Undesignated	Designated	Total
Adjusted Operating Expenses (Step 2)	$1,072,441	$1,455,988	$2,528,429
Total Target Pilot Compensation (Step 4)	2,519,209	2,519,209	5,038,418
Working Capital Fund (Step 5)	141,152	156,225	297,377
Total Revenue Needed	3,732,802	4,131,422	7,864,224

TABLE 18—REVENUE NEEDED FOR DISTRICT THREE

	Undesignated	Designated	Total
Adjusted Operating Expenses (Step 2)	$1,703,896	$529,817	$2,233,713
Total Target Pilot Compensation (Step 4)	5,758,192	1,439,548	7,197,740
Working Capital Fund (Step 5)	293,260	77,396	370,656
Total Revenue Needed	7,755,348	2,046,761	9,802,109

G. Step 7: Calculate Initial Base Rates

Having determined the revenue needed for each area in the previous six steps, the Coast Guard divides that number by the expected number of hours of traffic to develop an hourly rate. Step 7 is a two-part process. In the first part, we calculate the 10-year average of traffic in each district. Because we are calculating separate figures for designated and undesignated waters, there are two parts for each calculation. The calculations are shown in tables 19 through 21.

TABLE 19—TIME ON TASK FOR DISTRICT ONE

Year	Designated	Undesignated
2018	6,943	8,445
2017	7,605	8,679
2016	5,434	6,217
2015	5,743	6,667
2014	6,810	6,853
2013	5,864	5,529
2012	4,771	5,121
2011	5,045	5,377
2010	4,839	5,649
2009	3,511	3,947
Average	5,657	6,248

TABLE 20—TIME ON TASK FOR DISTRICT TWO

Year	Undesignated	Designated
2018	6,150	6,655
2017	5,139	6,074
2016	6,425	5,615
2015	6,535	5,967
2014	7,856	7,001
2013	4,603	4,750
2012	3,848	3,922
2011	3,708	3,680
2010	5,565	5,235
2009	3,386	3,017
Average	5,322	5,192

TABLE 21—TIME ON TASK FOR DISTRICT THREE

Year	Undesignated	Designated
2018	19,967	3,455
2017	20,955	2,997
2016	23,421	2,769
2015	22,824	2,696
2014	25,833	3,835
2013	17,115	2,631
2012	15,906	2,163
2011	16,012	1,678
2010	20,211	2,461
2009	12,520	1,820
Average	19,476	2,651

Next, we derive the initial hourly rate by dividing the revenue needed by the average number of hours for each area. This produces an initial rate needed to produce the revenue needed for each area, assuming the amount of traffic is as expected. The calculations for each area are set forth in tables 22 through 24.

TABLE 22—INITIAL RATE CALCULATIONS FOR DISTRICT ONE

	Designated	Undesignated
Revenue needed (Step 6)	$5,265,136	$4,006,716
Average time on task (hours)	5,657	6,248
Initial rate	$931	$641

TABLE 23—INITIAL RATE CALCULATIONS FOR DISTRICT TWO

	Undesignated	Designated
Revenue needed (Step 6)	$3,732,802	$4,131,422
Average time on task (hours)	5,322	5,192
Initial rate	$701	$796

TABLE 24—INITIAL RATE CALCULATIONS FOR DISTRICT THREE

	Undesignated	Designated
Revenue needed (Step 6)	$7,755,348	$2,046,761
Average time on task (hours)	19,476	2,651
Initial rate	$398	$772

H. Step 8: Calculate Average Weighting Factors by Area

In this step, the Coast Guard calculates the average weighting factor for each designated and undesignated area. We collect the weighting factors, as set forth in 46 CFR 401.400, for each vessel trip. Using this database, we calculate the average weighting factor for each area using the data from each vessel transit from 2014 onward, as shown in tables 25 through 30.

TABLE 25—AVERAGE WEIGHTING FACTOR FOR DISTRICT 1, DESIGNATED AREAS

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 1 (2014)	31	1	31
Class 1 (2015)	41	1	41
Class 1 (2016)	31	1	31
Class 1 (2017)	28	1	28
Class 1 (2018)	54	1	54
Class 2 (2014)	285	1.15	327.75
Class 2 (2015)	295	1.15	339.25
Class 2 (2016)	185	1.15	212.75
Class 2 (2017)	352	1.15	404.8
Class 2 (2018)	559	1.15	642.85
Class 3 (2014)	50	1.3	65

TABLE 25—AVERAGE WEIGHTING FACTOR FOR DISTRICT 1, DESIGNATED AREAS—Continued

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 3 (2015)	28	1.3	36.4
Class 3 (2016)	50	1.3	65
Class 3 (2017)	67	1.3	87.1
Class 3 (2018)	86	1.30	111.8
Class 4 (2014)	271	1.45	392.95
Class 4 (2015)	251	1.45	363.95
Class 4 (2016)	214	1.45	310.3
Class 4 (2017)	285	1.45	413.25
Class 4 (2018)	393	1.45	569.85
Total	3,556		4,528
Average weighting factor (weighted transits/number of transits)		1.27	

TABLE 26—AVERAGE WEIGHTING FACTOR FOR DISTRICT 1, UNDESIGNATED AREAS

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 1 (2014)	25	1	25
Class 1 (2015)	28	1	28
Class 1 (2016)	18	1	18
Class 1 (2017)	19	1	19
Class 1 (2018)	22	1	22
Class 2 (2014)	238	1.15	273.7
Class 2 (2015)	263	1.15	302.45
Class 2 (2016)	169	1.15	194.35
Class 2 (2017)	290	1.15	333.5
Class 2 (2018)	352	1.15	404.8
Class 3 (2014)	60	1.3	78
Class 3 (2015)	42	1.3	54.6
Class 3 (2016)	28	1.3	36.4
Class 3 (2017)	45	1.3	58.5
Class 3 (2018)	63	1.30	81.9
Class 4 (2014)	289	1.45	419.05
Class 4 (2015)	269	1.45	390.05
Class 4 (2016)	222	1.45	321.9
Class 4 (2017)	285	1.45	413.25
Class 4 (2018)	382	1.45	553.9
Total	3,109		4,028.35
Average weighting factor (weighted transits/number of transits)		1.30	

TABLE 27—AVERAGE WEIGHTING FACTOR FOR DISTRICT 2, UNDESIGNATED AREAS

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 1 (2014)	31	1	31
Class 1 (2015)	35	1	35
Class 1 (2016)	32	1	32
Class 1 (2017)	21	1	21
Class 1 (2018)	37	1	37
Class 2 (2014)	356	1.15	409.4
Class 2 (2015)	354	1.15	407.1
Class 2 (2016)	380	1.15	437
Class 2 (2017)	222	1.15	255.3
Class 2 (2018)	123	1.15	141.45
Class 3 (2014)	20	1.3	26
Class 3 (2015)	0	1.3	0
Class 3 (2016)	9	1.3	11.7
Class 3 (2017)	12	1.3	15.6
Class 3 (2018)	3	1.3	3.9
Class 4 (2014)	636	1.45	922.2
Class 4 (2015)	560	1.45	812
Class 4 (2016)	468	1.45	678.6
Class 4 (2017)	319	1.45	462.55
Class 4 (2018)	196	1.45	284.2

TABLE 27—AVERAGE WEIGHTING FACTOR FOR DISTRICT 2, UNDESIGNATED AREAS—Continued

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Total	3,814		5,023
Average weighting factor (weighted transits/number of transits)		1.32	

TABLE 28—AVERAGE WEIGHTING FACTOR FOR DISTRICT 2, DESIGNATED AREAS

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 1 (2014)	20	1	20
Class 1 (2015)	15	1	15
Class 1 (2016)	28	1	28
Class 1 (2017)	15	1	15
Class 1 (2018)	42	1	42
Class 2 (2014)	237	1.15	272.55
Class 2 (2015)	217	1.15	249.55
Class 2 (2016)	224	1.15	257.6
Class 2 (2017)	127	1.15	146.05
Class 2 (2018)	153	1.15	175.95
Class 3 (2014)	8	1.3	10.4
Class 3 (2015)	8	1.3	10.4
Class 3 (2016)	4	1.3	5.2
Class 3 (2017)	4	1.3	5.2
Class 3 (2018)	14	1.30	18.2
Class 4 (2014)	359	1.45	520.55
Class 4 (2015)	340	1.45	493
Class 4 (2016)	281	1.45	407.45
Class 4 (2017)	185	1.45	268.25
Class 4 (2018)	379	1.45	549.55
Total	2,660		3,509.9
Average weighting factor (weighted transits/number of transits)		1.32	

TABLE 29—AVERAGE WEIGHTING FACTOR FOR DISTRICT 3, UNDESIGNATED AREAS

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Area 6:			
Class 1 (2014)	45	1	45
Class 1 (2015)	56	1	56
Class 1 (2016)	136	1	136
Class 1 (2017)	148	1	148
Class 1 (2018)	103	1	103
Class 2 (2014)	274	1.15	315.1
Class 2 (2015)	207	1.15	238.05
Class 2 (2016)	236	1.15	271.4
Class 2 (2017)	264	1.15	303.6
Class 2 (2018)	169	1.15	194.35
Class 3 (2014)	15	1.3	19.5
Class 3 (2015)	8	1.3	10.4
Class 3 (2016)	10	1.3	13
Class 3 (2018)	9	1.30	11.7
Class 3 (2017)	19	1.3	24.7
Class 4 (2014)	394	1.45	571.3
Class 4 (2015)	375	1.45	543.75
Class 4 (2016)	332	1.45	481.4
Class 4 (2017)	367	1.45	532.15
Class 4 (2018)	337	1.45	488.65
Total for Area 6	3,504		4,507.05
Area 8:			
Class 1 (2014)	3	1	3
Class 1 (2015)	0	1	0
Class 1 (2016)	4	1	4
Class 1 (2017)	4	1	4
Class 1 (2018)	0	1	0
Class 2 (2014)	177	1.15	203.55
Class 2 (2015)	169	1.15	194.35

TABLE 29—AVERAGE WEIGHTING FACTOR FOR DISTRICT 3, UNDESIGNATED AREAS—Continued

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 2 (2016)	174	1.15	200.1
Class 2 (2017)	151	1.15	173.65
Class 2 (2018)	102	1.15	117.3
Class 3 (2014)	3	1.3	3.9
Class 3 (2015)	0	1.3	0
Class 3 (2016)	7	1.3	9.1
Class 3 (2017)	18	1.3	23.4
Class 3 (2018)	7	1.30	9.1
Class 4 (2014)	243	1.45	352.35
Class 4 (2015)	253	1.45	366.85
Class 4 (2016)	204	1.45	295.8
Class 4 (2017)	269	1.45	390.05
Class 4 (2018)	188	1.45	272.6
Total for Area 8	1,976		2,623.1
Combined total	5,480		7,130.15
Average weighting factor (weighted transits/number of transits)		1.30	

TABLE 30—AVERAGE WEIGHTING FACTOR FOR DISTRICT 3, DESIGNATED AREAS

Vessel class/year	Number of transits	Weighting factor	Weighted transits
Class 1 (2014)	27	1	27
Class 1 (2015)	23	1	23
Class 1 (2016)	55	1	55
Class 1 (2017)	62	1	62
Class 1 (2018)	47	1	47
Class 2 (2014)	221	1.15	254.15
Class 2 (2015)	145	1.15	166.75
Class 2 (2016)	174	1.15	200.1
Class 2 (2017)	170	1.15	195.5
Class 2 (2018)	126	1.15	144.9
Class 3 (2014)	4	1.3	5.2
Class 3 (2015)	0	1.3	0
Class 3 (2016)	6	1.3	7.8
Class 3 (2017)	14	1.3	18.2
Class 3 (2018)	6	1.3	7.8
Class 4 (2014)	321	1.45	465.45
Class 4 (2015)	245	1.45	355.25
Class 4 (2016)	191	1.45	276.95
Class 4 (2017)	234	1.45	339.3
Class 4 (2018)	225	1.45	326.25
Total	2,296		2,977.6
Average weighting factor (weighted transits/number of transits)		1.30	

I. Step 9: Calculate Revised Base Rates

In this step, the Coast Guard revised the base rates so that once the impact of the weighting factors are considered, the total cost of pilotage will be equal to the revenue needed. To do this, we divide the initial base rates, calculated in Step 7, by the average weighting factors, calculated in Step 8, as shown in table 31.

TABLE 31—REVISED BASE RATES

Area	Initial rate (Step 7)	Average weighting factor (Step 8)	Revised rate (initial rate/ average weighting factor)
District One: Designated	$931	1.27	$733
District One: Undesignated	641	1.30	493
District Two: Undesignated	701	1.32	531
District Two: Designated	796	1.32	603

TABLE 31—REVISED BASE RATES—Continued

Area	Initial rate (Step 7)	Average weighting factor (Step 8)	Revised rate (initial rate/ average weighting factor)
District Three: Undesignated	398	1.30	306
District Three: Designated	772	1.30	594

J. Step 10: Review and Finalize Rates

In this step, the Director reviews the rates set forth by the staffing model and ensures that they meet the goal of ensuring safe, efficient, and reliable pilotage. To establish that the rates do meet the goal of ensuring safe, efficient and reliable pilotage, the Director considered whether the rates incorporate appropriate compensation for pilots to handle heavy traffic periods and whether there are sufficient pilots to handle those heavy traffic periods. Also, the Director considered whether the rates will cover operating expenses and infrastructure costs, and took average traffic and weighting factors into consideration. Finally, in giving consideration to the public interest, we estimated that the new shipping rates would not have a negative impact on the competitive market for regional shipping services. Based on this information, the Director is not establishing any alterations to the rates in this step. We then modified the text in § 401.405(a) to reflect the final rates, also shown in table 32.

TABLE 32—FINAL RATES

Area	Name	Final 2018 pilotage rate	Proposed 2019 pilotage rate	Final 2019 pilotage rate
District One: Designated	St. Lawrence River	$653	$698	$733
District One: Undesignated	Lake Ontario	435	492	493
District Two: Undesignated	Lake Erie	497	530	531
District Two: Designated	Navigable waters from Southeast Shoal to Port Huron, MI.	593	632	603
District Three: Undesignated	Lakes Huron, Michigan, and Superior	271	304	306
District Three: Designated	St. Mary's River	600	602	594

K. Surcharges

Because there are several applicant pilots in 2019, the Coast Guard is levying surcharges to cover the costs needed for training expenses. Consistent with previous years, we are assigning a cost of $150,000 per applicant pilot. To develop the surcharge, we multiply the number of applicant pilots by the average cost per pilot to develop a total amount of training costs needed, and then impose that amount as a surcharge to all areas in the respective district, consisting of a percentage of revenue needed. In this year, there are two applicant pilots for District One, one applicant pilot for District Two, and four applicant pilots for District Three. The calculations to develop the surcharges are shown in table 33. We note that while the percentages are rounded for simplicity, such rounding does not impact the revenue generated, as surcharges can no longer be collected once the surcharge total has been attained.

TABLE 33—SURCHARGE CALCULATIONS

	District One	District Two	District Three
Number of applicant pilots	2	1	4
Total applicant training costs	$300,000	$150,000	$600,000
Revenue needed (Step 6)	$9,271,852	$7,864,224	$9,802,109
Total surcharge as percentage (total training costs/revenue)	3%	2%	6%

VII. Regulatory Analyses

The Coast Guard developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes or Executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (Reducing Regulation and

Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. Because this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. *See* the OMB Memorandum titled, ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017). A regulatory analysis follows.

The purpose of this rulemaking is to establish new base pilotage rates and surcharges for training. The Great Lakes Pilotage Act of 1960 requires that rates be established or reviewed and adjusted each year. The Act requires that base rates be established by a full ratemaking at least once every five years, and in years when base rates are not established, they must be reviewed and, if necessary, adjusted. The last full ratemaking was concluded in June of 2018. Table 34 summarizes the affected population, costs, and benefits of the rate changes. The Coast Guard estimates an increase in cost of approximately $2.83 million to industry as a result of the change in revenue needed in 2019 when compared to the revenue needed in 2018.

TABLE 34—ECONOMIC IMPACTS DUE TO RATE CHANGES

Change	Description	Affected population	Costs	Benefits
Rate Changes	Under the Great Lakes Pilotage Act of 1960, the Coast Guard is required to review and adjust base pilotage rates annually.	Owners and operators of 256 vessels journeying the Great Lakes system annually, 51 U.S. Great Lakes pilots, and 3 pilotage associations.	$2,831,743 Due to change in revenue needed for 2019 ($27,988,185) from revenue needed for 2018 ($25,156,442) as shown in Table 36 below.	—New rates cover an association's necessary and reasonable operating expenses. —Promotes safe, efficient, and reliable pilotage service on the Great Lakes. —Provides fair compensation, adequate training, and sufficient rest periods for pilots. —Ensures the association receives sufficient revenues to fund future improvements.

Table 35 summarizes the changes in the regulatory analysis from the NPRM to the final rule. The Coast Guard made these changes either as a result of public comments received after publication of the NPRM, or to incorporate more recent inflation, security, and traffic data that became available after the publication of the NPRM. An in-depth discussion of these comments is located in Section V of the preamble; ''Discussion of Comments.''

TABLE 35—SUMMARY OF CHANGES FROM NPRM TO FINAL RULE

Element of the analysis	NPRM	Final rule	Resulting change in RA
Changes Resulting from Public Comments and Errors in the NPRM			
Operating Expenses (Step 1)	Omitted District 1 capital expenditures.	Corrected this error to account for District 1 capital expenditures totaling $466,940.	Data affects the calculation of projected revenues.
	Omitted the cost of health care benefits for applicant pilots in both District 2 and District 3.	Corrected this error and adjusted the operating expenses to both District 2 and District 3 by $60,031.	
	Incorrectly deducted $1,292 from District 3 for legal fees.	Removed deduction	
	As the result of a mathematical error, we accidently excluded $77,051 worth of District 2 administrative expenses from the their total operating expenses.	Corrected this error	
	Total Operating Expenses from Step 1 (the sum of the totals from Tables 3–5): $6,484,651.	Total Operating Expenses from Step 1 (the sum of the totals from Tables 3–5): $7,149,996.	
Traffic and Transit data	Used incorrect 2017 traffic numbers for District 3.	Corrected this error	No impact on RA. Affects the calculation of the base rates, but not the projected revenues.

TABLE 35—SUMMARY OF CHANGES FROM NPRM TO FINAL RULE—Continued

Element of the analysis	NPRM	Final rule	Resulting change in RA
Pilotage Costs as a Percentage of Total Vessel Costs.	The RA included this analysis, which calculated pilotage costs as a percentage of total voyage costs.	Removed this analysis from the RA based on public comments on the underlying data.	Analysis is no longer included in the RA.
Changes that Incorporate the Most Recently Available Data			
Inflation and securities data	Used inflation and securities data through 2017, which was the most current year available.	Uses 2018 data when applicable and available.	Data affects the calculation of projected revenues.
Traffic and Transit data	Used traffic and transit data through 2017, which was the most current year available.	Uses 2018 data	No impact on RA. Affects the calculation of the base rates, but not the projected revenues.

The Coast Guard is required to review and adjust pilotage rates on the Great Lakes annually. See Sections III and IV of this preamble for detailed discussions of the legal basis and purpose for this rulemaking and for background information on Great Lakes pilotage ratemaking. Based on our annual review for this rulemaking, we are adjusting the pilotage rates for the 2019 shipping season to generate sufficient revenues for each district to reimburse its necessary and reasonable operating expenses, fairly compensate trained and rested pilots, and provide an appropriate working capital fund to use for improvements. The rate changes in this rulemaking will lead to an increase in the cost per unit of service to shippers in all three districts, and result in an estimated annual cost increase to shippers. We estimate this rule will increase the total payments made by shippers during the 2019 shipping season by approximately $2,831,743 when compared with total payments that were estimated in 2018, which is an 11 percent increase (table 36).[81]

A detailed discussion of our economic impact analysis follows.

Affected Population

This rule will impact U.S. Great Lakes pilots, the three pilot associations, and the owners and operators of oceangoing vessels that transit the Great Lakes annually. As discussed in Step 3 in Section VI.C of this preamble, there will be 51 pilots working during the 2019 shipping season. The shippers affected by these rate changes are those owners and operators of domestic vessels operating ''on register'' (employed in foreign trade) and owners and operators of non-Canadian foreign vessels on routes within the Great Lakes system. These owners and operators must have pilots or pilotage service as required by 46 U.S.C. 9302. There is no minimum tonnage limit or exemption for these vessels. The statute applies only to commercial vessels and not to recreational vessels. U.S.-flagged vessels not operating on register and Canadian ''lakers,'' which account for most commercial shipping on the Great Lakes, are not required by 46 U.S.C. 9302 to have pilots. However, these U.S.- and Canadian-flagged lakers may voluntarily choose to engage a Great Lakes registered pilot. Vessels that are U.S.-flagged may opt to have a pilot for varying reasons, such as unfamiliarity with designated waters and ports, or for insurance purposes.

The Coast Guard used billing information from the years 2015 through 2017 from the Great Lakes Pilotage Management System (GLPMS) to estimate the average annual number of vessels affected by the rate adjustment. The GLPMS tracks data related to managing and coordinating the dispatch of pilots on the Great Lakes, and billing in accordance with the services. In Step 7 of the methodology, we use a 10-year average to estimate the traffic. We use three years of the most recent billing data to estimate the affected population. When we reviewed 10 years of the most recent billing data, we found the data included vessels that have not used pilotage services in recent years. We believe using three years of billing data is a better representation of the vessel population that is currently using pilotage services and would be impacted by this rulemaking. We found that 448 unique vessels used pilotage services during the years 2015 through 2017. That is, these vessels had a pilot dispatched to the vessel, and billing information was recorded in the GLPMS. Of these vessels, 418 were foreign-flagged vessels and 30 were U.S.-flagged vessels. As previously stated, U.S.-flagged vessels not operating on register are not required to have a registered pilot per 46 U.S.C. 9302, but they can voluntarily choose to have one.

Numerous factors affect vessel traffic which varies from year to year. Therefore, rather than the total number of vessels over the time period, an average of the unique vessels using pilotage services from the years 2015 through 2017 is the best representation of vessels estimated to be affected by the rate in this rulemaking. From 2015 through 2017, an average of 256 vessels used pilotage services annually.[82] On average, 241 of these vessels were foreign-flagged vessels and 15 were U.S.-flagged vessels that voluntarily opted into the pilotage service.

Total Cost to Shippers

The rate changes resulting from this adjustment to the rates will add new costs to shippers in the form of higher payments to pilots. The Coast Guard estimates the effect of the rate changes on shippers by comparing the total projected revenues needed to cover costs in 2018 with the total projected revenues to cover costs in 2019, including any temporary surcharges we have authorized. We set pilotage rates so that pilot associations receive enough revenue to cover their necessary and reasonable expenses. Shippers pay these rates when they have a pilot as required by 46 U.S.C. 9302. Therefore, the aggregate payments of shippers to pilot associations are equal to the projected necessary revenues for pilot associations. The revenues each year represent the total costs that shippers must pay for pilotage services, and the change in revenue from the previous year is the additional cost to shippers discussed in this rule.

[81] Total payments across all three districts are equal to the increase in payments incurred by shippers as a result of the rate changes plus the temporary surcharges applied to traffic in Districts One, Two, and Three.

[82] Some vessels entered the Great Lakes multiple times in a single year, affecting the average number of unique vessels utilizing pilotage services in any given year.

The impacts of the rate changes on shippers are estimated from the District pilotage projected revenues (shown in tables 15 through 17 of this preamble) and the surcharges described in Section VI.K of this preamble. The Coast Guard estimates that for the 2019 shipping season, the projected revenue needed for all three districts is $26,938,185. This $26,938,185 in revenue does not include the temporary surcharges on traffic in Districts One, Two, and Three which will be applied for the duration of the 2019 season in order for the pilotage associations to recover training expenses incurred for applicant pilots. We estimate that the pilotage associations will require $300,000, $150,000, and $600,000 in revenue for applicant training expenses in Districts One, Two, and Three, respectively. This will represent a total cost of $1,050,000 to shippers during the 2019 shipping season. Adding the projected revenue of $26,938,185 to the surcharges, we estimate the pilotage associations' total projected revenue needed for 2019 will be $27,988,185.

To estimate the additional cost to shippers from this rule, the Coast Guard compared the 2019 total projected revenues to the 2018 projected revenues. Because we review and prescribe rates for the Great Lakes Pilotage annually, the effects are estimated as a single-year cost rather than annualized over a 10-year period. In the 2018 rulemaking, [83] we estimated the total projected revenue needed for 2018, including surcharges, as $25,156,442. This is the best approximation of 2018 revenues as, at the time of this publication, we do not have enough audited data available for the 2018 shipping season to revise these projections. Table 36 shows the revenue projections for 2018 and 2019 and details the additional cost increases to shippers by area and district as a result of the rate changes and temporary surcharges on traffic in Districts One, Two, and Three.

TABLE 36—EFFECT OF THE RULE BY AREA AND DISTRICT

[$U.S.; non-discounted]

Area	Revenue needed in 2018	2018 Temporary surcharge	Total 2018 projected revenue	Revenue needed in 2019	2019 Temporary surcharge	Total 2019 projected revenue	Additional costs of this rule
Total, District 1	$7,988,670	$300,000	$8,288,670	$9,271,852	$300,000	$9,571,852	$1,283,182
Total, District 2	7,230,300	150,000	7,380,300	7,864,224	150,000	8,014,224	633,924
Total, District 3	8,887,472	600,000	9,487,472	9,802,109	600,000	10,402,109	914,637
System Total	24,106,442	1,050,000	25,156,442	26,938,185	1,050,000	27,988,185	2,831,743

The resulting difference between the projected revenue in 2018 and the projected revenue in 2019 is the annual change in payments from shippers to pilots as a result of the rate change imposed by this rule. The effect of the rate change to shippers varies by area and district. The rate changes, after taking into account the increase in pilotage rates and the addition of temporary surcharges, will lead to affected shippers operating in District One, District Two, and District Three experiencing an increase in payments of $1,283,182, $633,924, and $914,637, respectively, over the previous year. The overall adjustment in payments will be an increase in payments by shippers of $2,831,743 across all three districts (an 11 percent increase over 2018). Again, because the Coast Guard reviews and sets rates for Great Lakes Pilotage annually, we estimate the impacts as single-year costs rather than annualizing them over a 10-year period.

Table 37 shows the difference in revenue by component from 2018 to 2019.[84] The majority of the increase in revenue is due to the inflation of operating expenses and to the addition of two pilots who were authorized in the 2018 rule. These two pilots were in training in 2018 and will become full-time working pilots at the beginning of the 2019 shipping season. The target compensation for these pilots is $359,887 per pilot. The addition of these pilots to full working status accounts for $719,774 of the increase ($1,082,472 when also including the effect of increasing compensation for 49 pilots). The remaining amount is attributed to increases in the working capital fund.

TABLE 37—DIFFERENCE IN REVENUE BY COMPONENT

Revenue component	Revenue needed in 2018	Revenue needed in 2019	Difference (2019 Revenue −2018 Revenue)	Percentage increase from previous year (%)
Adjusted Operating Expenses	$5,965,599	$7,565,310	$1,599,711	27
Total Target Pilot Compensation	17,271,765	18,354,237	1,082,472	6
Working Capital Fund	869,078	1,018,638	149,560	17
Total Revenue Needed, without Surcharge	24,106,442	26,938,185	2,831,743	12
Surcharge	1,050,000	1,050,000	0	0
Total Revenue Needed, with Surcharge	25,156,442	27,988,185	2,831,743	11

[83] The 2018 projected revenues are from the 2018 Great Lakes Pilotage Ratemaking final rule (83 FR 26189), Table 41.

[84] The 2018 projected revenues are from the 2018 final rule (83 FR 26189), table 41. The 2019 projected revenues are from tables 15–17 of this rule.

Benefits

This rule will allow the Coast Guard to meet the requirements in 46 U.S.C. 9303 to review the rates for pilotage services on the Great Lakes. The rate changes will promote safe, efficient, and reliable pilotage service on the Great Lakes by: (1) Ensuring that rates cover an association's operating expenses; (2) providing fair pilot compensation, adequate training, and sufficient rest periods for pilots; and (3) ensuring the association produces enough revenue to fund future improvements. The rate changes will also help recruit and retain pilots, which will ensure a sufficient number of pilots to meet peak shipping demand, helping to reduce delays caused by pilot shortages.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, the Coast Guard has considered whether this rule will have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For the rule, the Coast Guard reviewed recent company size and ownership data for the vessels identified in the GLPMS, and we reviewed business revenue and size data provided by publicly available sources such as Manta [85] and ReferenceUSA.[86] As described in Section VII.A of this preamble, Regulatory Planning and Review, we found that a total of 448 unique vessels used pilotage services from 2015 through 2017. These vessels are owned by 57 entities. We found that of the 57 entities that own or operate vessels engaged in trade on the Great Lakes affected by this rule, 47 are foreign entities that operate primarily outside the United States. The remaining ten entities are U.S. entities. We compared the revenue and employee data found in the company search to the Small Business Administration's (SBA) small business threshold as defined in the SBA's Table of Small Business Size Standards [87] to determine how many of these companies are small entities. Table 38 shows the North American Industry Classification System (NAICS) codes of the U.S. entities and the small entity standard size established by the SBA.

TABLE 38—NAICS CODES AND SMALL ENTITIES SIZE STANDARDS

NAICS	Description	Small business size standard
238910	Site Preparation Contractors	$15 million.
483211	Inland Water Freight Transportation	750 employees.
487210	Scenic & Sightseeing Transportation, Water	$7.5 million.
488330	Navigational Services to Shipping	$38.5 million.
488510	Freight Transportation Arrangement	$15 million.
561510	Travel Agencies	$20.5 million.

Of the ten U.S. entities, nine exceed the SBA's small business standards for small businesses. To estimate the potential impact on the one small entity, the Coast Guard used their 2017 invoice data to estimate their pilotage costs in 2019. We increased their 2017 costs to account for the changes in pilotage rates resulting from this rule and the 2018 final rule (83 FR 26189).[88] We then estimated the change in cost to this entity resulting from this rule by subtracting their estimated 2018 costs from their estimated 2019 costs, and compared this change with their annual revenue. We also compared their total estimated 2019 pilotage cost to their annual revenue and in both cases their estimated pilotage cost was below 1 percent of their annual revenue. In addition, we do not expect the rule will significantly impact any of these ten entities, including the one small entity, because these U.S. entities operate U.S.-flagged vessels and are not required to have pilots as required by 46 U.S.C. 9302.

In addition to the owners and operators of vessels affected by this rule, there are three U.S. entities that will be affected by this rule that receive revenue from pilotage services. These are the three pilot associations that provide and manage pilotage services within the Great Lakes districts. Two of the associations operate as partnerships, and one operates as a corporation. These associations are designated with the same NAICS industry classification and small-entity size standards described above, but they have fewer than 500 employees; combined, they have approximately 65 employees in total, and, therefore, they are designated as small entities. The Coast Guard expects no adverse effect on these entities from this rule because all associations will receive enough revenue to balance the projected expenses associated with the projected number of bridge hours (time on task) and pilots.

The Coast Guard did not find any small not-for-profit organizations that are independently owned and operated and are not dominant in their fields that will be impacted by this rule. We did not find any small governmental jurisdictions with populations of fewer than 50,000 people that will be impacted by this rule. Based on this analysis, we conclude this rulemaking will not affect a substantial number of small entities, nor have a significant economic impact on any of the affected entities.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, the Coast Guard offers to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. We will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

[85] See *https://www.manta.com/.*

[86] See *http://resource.referenceusa.com/.*

[87] See: *https://www.sba.gov/document/support--table-size-standards.* SBA has established a Table of Small Business Size Standards, which sets small business sized standards by NAICS code. A size standard, which is usually stated in number of employees or average annual receipts (''revenues''), represents the largest size that a business (including its subsidiaries and affiliates) may be considered in order to remain classified as a small business for SBA and Federal contracting programs.

[88] For confidentiality reasons we are unable to provide this vessel's 2017 pilotage costs or its estimated 2018 and 2019 pilotage costs.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995, (44 U.S.C. 3501–3520). This rule will not change the burden in the collection currently approved by OMB under OMB Control Number 1625–0086, Great Lakes Pilotage Methodology.

E. Federalism

A rule has implications for federalism under Executive Order 13132 (Federalism) if it has a substantial direct effect on 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 Coast Guard has analyzed this final rule under Executive Order 13132 and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132. Our analysis follows.

Congress directed the Coast Guard to establish ''rates and charges for pilotage services.'' *See* 46 U.S.C. 9303(f). This regulation is issued pursuant to that statute and is preemptive of State law as specified in 46 U.S.C. 9306. Under 46 U.S.C. 9306, a ''State or political subdivision of a State may not regulate or impose any requirement on pilotage on the Great Lakes.'' As a result, States or local governments are expressly prohibited from regulating within this category. Therefore, this rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, the Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, Executive Order 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this rule has implications for federalism under Executive Order 13132, please contact the person listed in the **FOR FURTHER INFORMATION** section of this preamble.

F. Unfunded Mandates Reform Act

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

G. Taking of Private Property

This final rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

H. Civil Justice Reform

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 (Civil Justice Reform) to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

The Coast Guard has analyzed this final rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This rule is not an economically significant rule and will not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

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

K. Energy Effects

The Coast Guard has analyzed this rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the Administrator of OMB's Office of Information and Regulatory Affairs has not designated it as a significant energy action.

L. Technical Standards

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

The Coast Guard has analyzed this rule under Department of Homeland Security Management Directive 023–01and Commandant Instruction M16475.lD (COMDTINST M16475.1D), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is not likely to have a significant effect on the human environment. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under the **ADDRESSES** section of this preamble. This rule is categorically excluded under paragraph A3 of table 1, particularly subparts (a), (b), and (c) in Appendix A of DHS Directive 023–01(series). CATEX A3 pertains to promulgation of rules and procedures that are: (a) Strictly administrative or procedural in nature; (b) that implement, without substantive change, statutory or regulatory requirements; or (c) that implement, without substantive change, procedures, manuals, and other guidance documents. This rule adjusts base pilotage rates and surcharges for administering the 2019 shipping season in accordance with applicable statutory and regulatory mandates, and also makes technical changes to the Great Lakes pilotage ratemaking methodology.

List of Subjects

46 CFR Part 401

Administrative practice and procedure, Great Lakes, Navigation (water), Penalties, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 404

Great Lakes, Navigation (water), Seamen.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR part 401 as follows:

PART 401—GREAT LAKES PILOTAGE REGULATIONS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: 46 U.S.C. 2103, 2104(a), 6101, 7701, 8105, 9303, 9304; Department of Homeland Security Delegation No. 0170.1(II)(92.a), (92.d), (92.e), (92.f).

■ 2. Amend § 401.405 by revising paragraph (a) to read as follows:

§ 401.405 Pilotage rates and charges.

(a) The hourly rate for pilotage service on—

(1) The St. Lawrence River is $733;

(2) Lake Ontario is $493;

(3) Lake Erie is $531;

(4) The navigable waters from Southeast Shoal to Port Huron, MI is $603;

(5) Lakes Huron, Michigan, and Superior is $306; and

(6) The St. Mary's River is $594.

* * * * *

PART 404—GREAT LAKES PILOTAGERATEMAKING

■ 3. The authority citation for part 404 continues to read as follows:

Authority: 46 U.S.C. 2103, 2104(a), 9303, 9304; Department of Homeland Security Delegation No. 0170.1(II)(92.a), (92.f).

§ 404.2 [Amended]

■ 4. Amend § 404.2 by removing paragraph (b)(6).

§ 404.104 [Amended]

■ 5. Amend § 404.104 in paragraph (c) by removing the reference ''§ 404.103(d)'' and adding in its place ''§ 404.103''.

Dated: May 6, 2019.

John P. Nadeau,

Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2019–09657 Filed 5–9–19; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 181218999–9402–02]

RIN 0648–BI67

Magnuson-Stevens Act Provisions; Fisheries off West Coast States; Pacific Coast Groundfish Fishery; Annual Specifications and Management Measures for the 2019 Tribal and Non-Tribal Fisheries for Pacific Whiting, and Requirement To Consider Chinook Salmon Bycatch Before Reapportioning Tribal Whiting

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule for the 2019 Pacific whiting fishery under the authority of the Pacific Coast Groundfish Fishery Management Plan, the Magnuson-Stevens Fishery Conservation and Management Act, and the Pacific Whiting Act of 2006. This final rule announces the 2019 U.S. Total Allowable Catch of 441,433 metric tons (mt) of Pacific whiting, establishes a tribal allocation of 77,251 mt, establishes a set-aside for research and bycatch of 1,500 mt, and announces the allocations of Pacific whiting to the non-tribal fishery for 2019. This final rule also amends the provisions regarding reapportionment of the treaty tribes' whiting allocation to the non-treaty sectors to require that NMFS consider the level of Chinook salmon bycatch before reapportioning whiting. This rule is necessary to manage the Pacific whiting stock to Optimal Yield, ensure that the Pacific Coast Groundfish Fishery Management Plan is implemented in a manner consistent with treaty rights of four treaty tribes to fish for Pacific whiting in their ''usual and accustomed grounds and stations'' in common with non-tribal citizens, and to protect salmon stocks listed under the Endangered Species Act. The catch limits in this rule are intended to ensure the long-term sustainability of the Pacific whiting stock.

DATES: Effective May 10, 2019.

FOR FURTHER INFORMATION CONTACT: Miako Ushio (West Coast Region, NMFS), phone: 206–526–4644, and email: *Miako.Ushio@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

This final rule is accessible via the internet at the Office of the Federal Register website at *https://www.federalregister.gov.* Background information and documents are available at the NMFS West Coast Region website at *http://www.westcoast.fisheries.noaa.gov/fisheries/management/whiting/pacific_whiting.html* and at the Pacific Fishery Management Council (Council)'s website at *http://www.pcouncil.org/.*

The final environmental impact statement regarding Harvest Specifications and Management Measures for 2015–2016 and Biennial Periods Thereafter, and the Final Environmental Assessment for Pacific Coast Groundfish Fishery 2019–20 Harvest Specifications, Yelloweye Rebuilding Plan Revisions, and Management Measures, are available on the NMFS West Coast Region website at: *www.westcoast.fisheries.noaa.gov/publications/nepa/groundfish/groundfish_nepa_documents.html.*

Background

This final rule announces the total allowable catch (TAC) for Pacific whiting, which was determined under the terms of the Agreement with Canada on Pacific Hake/Whiting (Agreement) and the Pacific Whiting Act of 2006 (Whiting Act). The Agreement and the Whiting Act establish bilateral bodies to implement the terms of the Agreement. The bilateral bodies include: The Joint Management Committee (JMC), which recommends the annual catch level for Pacific whiting; the Joint Technical Committee (JTC), which conducts the Pacific whiting stock assessment; the Scientific Review Group (SRG), which reviews the stock assessment; and the Advisory Panel (AP), which provides stakeholder input to the JMC.

The Agreement establishes a default harvest policy of F–40 percent, which means a fishing mortality rate that would reduce the biomass to 40 percent of the estimated unfished level. The Agreement also allocates 73.88 percent of the TAC to the United States and 26.12 percent of the TAC to Canada. The JMC is primarily responsible for developing a TAC recommendation to the United States and Canada. The Secretary of Commerce, in consultation with the Secretary of State, has the authority to accept or reject this recommendation.

2019 Pacific Whiting Stock Assessment and Scientific Review

The JTC completed a stock assessment for Pacific whiting in February 2019.

This assessment is available at *http://www.westcoast.fisheries.noaa.gov/fisheries/management/whiting/pacific_whiting_treaty.html.* The assessment presents a model that depends primarily upon an acoustic survey biomass index and catches of the transboundary Pacific whiting stock to estimate the biomass of the current stock. The most recent survey, conducted collaboratively between the Canadian Department of Fisheries and Oceans and NMFS, was completed in 2017.

Pacific whiting spawning stock biomass has been relatively stable since 2017. The 2019 spawning biomass is estimated to be 1.3 million mt, an estimated 64 percent of unfished levels. The 2010 year class of Pacific whiting was very large, and the 2014 and 2016 year classes are estimated to be above average. The 2010, 2014, and 2016 year classes support the fishery at this time. In terms of relative health of the stock, the joint probability that the stock is both below 40 percent of unfished level and above the Agreement's F–40 percent default harvest rate is estimated to be 10.3 percent. As with past estimates, there is a considerable range of uncertainty associated with this estimate, because the youngest cohorts that make up a large portion of the survey biomass have not been observed for very long.

The JTC provided tables showing catch alternatives for 2019. Using the default F–40 percent harvest rule identified in the Agreement [Paragraph 1 of Article III] results in a coastwide TAC for 2019 of 725,593 mt. The stock assessment indicates that the coastal Pacific whiting stock is not overfished and overfishing is not occurring.

Summary of 2018 Fishery

Coast-wide fishery Pacific Hake landings averaged 233,645 mt from 1966 to 2018, with a low of 89,930 mt in 1980 and a peak of 440,942 mt in 2017. The coastwide catch in 2018 was the second largest on record at 410,443 mt out of a 597,500 mt adjusted coastwide TAC. Attainment in the U.S. was 71.4 percent of its quota (down 9 percent from 2017); in Canada it was 61.1 percent (up 6 percent from 2017).

In the U.S., the tribal sector was initially allocated 77,251 mt Pacific whiting, of which NMFS reallocated 40,000 mt inseason to non-tribal sectors on September 24, 2018 (83 FR 61569; November 30, 2018). The Makah Tribe was the only participant in the tribal sector, and caught approximately 5,700 mt of Pacific whiting in 2018. The U.S. non-tribal sector's catches compared to their final allocations were: C/P Sector: 116,073 of 136,912 mt; Mothership 67,129 of 96,644 mt; and Shorebased: 131,829 of 169,127 mt.

TAC Recommendation

The AP and JMC met March 4–5, 2019, in Vancouver, British Columbia in Canada, to develop advice on a 2019 coastwide TAC. The AP provided its 2019 TAC recommendation to the JMC on March 5, 2019. The JMC reviewed the advice of the JTC, the SRG, and the AP, and agreed on a TAC recommendation for transmittal to the United States and Canadian Governments.

The Agreement directs the JMC to base the catch limit recommendation on the default harvest rate unless scientific evidence demonstrates that a different rate is necessary to sustain the offshore Pacific whiting resource. After consideration of the 2019 stock assessment and other relevant scientific information, the JMC did not use the default harvest rate, and instead agreed on a more conservative approach, using the same catch limit as 2017 and 2018. Choosing a TAC well below the default level of F–40 percent was supported by a desire to minimize mortality of the 2016 year class, the scale of which is uncertain. This TAC advice was also based in part on an estimate from Canadian and U.S. industry members that the 2019 total coastwide harvest will be more similar to the 2017 level, approximately 440,000 mt, rather than the amount harvested in 2018, 410,000 mt. The JMC did not choose an even lower TAC, because of the presence of the strong 2010 and 2014 year classes. In the unlikely event the 2019 coastwide harvest reaches 500,000 mt, the beginning of year relative spawning biomass in 2020 is projected to be 61 percent of unfished biomass, which is well above target levels. The recommended TAC is projected to prevent overfishing and maintain the stock above overfished levels, but allows each Party and each fishing sector to maximize their harvesting opportunity to the extent of their relative respective capacities and interests.

The recommendation for an unadjusted 2019 U.S. TAC of 384,053 mt, plus 57,380 mt carryover of uncaught quota from 2018 results in an adjusted U.S. TAC of 441,433 mt for 2019 (73.88 percent of the coastwide TAC). This recommendation is consistent with the best available scientific information, provisions of the Agreement, and the Whiting Act. The recommendation was transmitted via letter to the United States and Canadian Governments on March 5, 2019. NMFS, under delegation of authority from the Secretary of Commerce, approved the adjusted TAC recommendation of 441,433 mt for U.S. fisheries on April 3, 2019.

Tribal Fishery Allocation

This final rule establishes the tribal allocation of Pacific whiting for 2019. NMFS issued a proposed rule regarding this allocation on March 15, 2019 (84 FR 9471). Since 1996, NMFS has been allocating a portion of the U.S. TAC of Pacific whiting to the tribal fishery. Regulations for the Pacific Coast Groundfish Fishery Management Plan specify that the tribal allocation is subtracted from the total U.S. Pacific whiting TAC. The tribal Pacific whiting fishery is managed separately from the non-tribal Pacific whiting fishery, and is not governed by limited entry or open access regulations or allocations.

The proposed rule described the tribal allocation as 17.5 percent of the U.S. TAC, and projected a range of potential tribal allocations for 2019 based on a range of U.S. TACs over the last 10 years (plus or minus 25 percent to capture variability in stock abundance). As described in the proposed rule, the resulting range of potential tribal allocations was 17,842 to 96,563 mt. Applying the approach described in the proposed rule, NMFS is establishing the 2019 tribal allocation of 77,251 mt (17.5 percent of the U.S. TAC) in this final rule. In 2009, NMFS, the states of Washington and Oregon, and the tribes with treaty rights to harvest whiting started a process to determine the long-term tribal allocation for Pacific whiting; however, no long-term allocation has been determined. While new scientific information or discussions with the relevant parties may impact that decision, the best available scientific information to date suggests that 77,251 mt is within the likely range of potential treaty right amounts.

As with prior tribal Pacific whiting allocations, this final rule is not intended to establish precedent for future Pacific whiting seasons, or for the determination of the total amount of whiting to which the Tribes are entitled under their treaty right. Rather, this rule adopts an interim allocation. The long-term tribal treaty amount will be based on further development of scientific information and additional coordination and discussion with and among the coastal tribes and the states of Washington and Oregon.

Harvest Guidelines and Allocations

In addition to the tribal allocation described in the proposed rule published on March 15, 2019 (84 FR

9471), this final rule establishes the fishery harvest guideline (HG), called the non-tribal allocation. NMFS did not include the HG in the tribal whiting proposed rule, for reasons related to timing and process. The HG had not yet been determined at the time the proposed rule was published. A recommendation on the coastwide and U.S. TAC for Pacific whiting for 2019, under the terms of the Agreement with Canada was approved by NMFS, under delegation of authority from the Secretary of Commerce, on April 3, 2019.

Although this was not part of the proposed rule, the environmental assessment for the 2019–2020 harvest specifications rule (see Electronic Access) analyzed a range of TAC alternatives for 2019, and the final 2019 TAC falls within this analyzed range. In addition, via the 2019–2020 harvest specifications rulemaking process, the public had an opportunity to comment on the 2019–2020 TACs for whiting, just as they did for all species in the groundfish FMP. NMFS follows this process because, unlike for all other groundfish species, the TAC for whiting is decided in a highly abbreviated annual process from February through April of every year, and the normal rulemaking process would not allow for the fishery to open with the new TAC on the annual season opening date of May 15. The 2019 fishery HG for Pacific whiting is 362,682 mt. This amount was determined by deducting the 77,251 mt tribal allocation and the 1,500 mt allocation for scientific research catch and fishing mortality in non-groundfish fisheries from the total U.S. TAC of 441,433 mt. The Council recommends the research and bycatch set-aside on an annual basis, based on estimates of scientific research catch and estimated bycatch mortality in non-groundfish fisheries.

The regulations further allocate the fishery HG among the three non-tribal sectors of the Pacific whiting fishery: The catcher/processor (C/P) Coop Program, the Mothership (MS) Coop Program, and the Shorebased Individual Fishing Quota (IFQ) Program. The C/P Coop Program is allocated 34 percent (123,312 mt for 2019), the MS Coop Program is allocated 24 percent (87,044 mt for 2019), and the Shorebased IFQ Program is allocated 42 percent (152,326.5 mt for 2019). The fishery south of 42° N lat. may not take more than 7,616 mt (5 percent of the Shorebased IFQ Program allocation) prior to May 15, the start of the primary Pacific whiting season north of 42° N lat.

TABLE 1—2019 PACIFIC WHITING ALLOCATIONS

Sector	2019 Pacific whiting allocation (mt)
Tribal	77,251
Catcher/Processor (C/P) Coop Program	123,312
Mothership (MS) Coop Program	87,044
Shorebased IFQ Program	152,326.5

Consideration of Chinook Salmon Bycatch Before Reapportioning Tribal Whiting

On December 11, 2017, NMFS completed an ESA Section 7(a)(2) biological opinion on the effects of the Pacific Coast Groundfish Fishery Management Plan on listed salmonids. Term and Condition 2c of the Biological Opinion states: ''No later than May 15th, 2019, NMFS will amend the provisions regarding reapportionment of the treaty tribes' whiting allocation to the non-treaty sectors to require that NMFS consider the level of Chinook bycatch when determining whether to reapportion whiting.''

This final rule amends the Pacific Coast Groundfish fishery regulations to require this consideration, and to identify what factors will be considered when determining whether to reapportion whiting. The purpose of this action is twofold. Reapportioning whiting that would not otherwise be used allows the non-tribal whiting fishery to continue fishing, thereby potentially impacting Chinook salmon, which occurs as bycatch in that fishery. The first purpose of the action is to issue regulatory changes that will minimize impacts to Chinook salmon from the whiting fishery. The second purpose is to protect the treaty rights of the tribes by preventing a reapportionment of Pacific whiting that could cause the entire whiting fishery, both tribal and non-tribal, to close via automatic action measures outlined at § 660.60(d)(1)(v), thereby limiting the tribal whiting fishery's opportunity to harvest their allocation.

Comments and Responses

On March 15, 2019, NMFS issued a proposed rule for the allocation and management of the 2018 tribal Pacific whiting fishery, and implementation of regulations requiring consideration of Chinook salmon bycatch before reapportioning tribal whiting (84 FR 9471). The comment period on the proposed rule closed on April 1, 2019. NMFS received three unique comment letters during the comment period on the proposed rule: One letter from Heather Mann, Executive Director of Midwater Trawlers Cooperative and Brent Paine, Executive Director of United Catcher Boats; one letter from Kristen McQuaw, Manager of Shoreside Whiting Cooperative; and one from Daniel Waldeck, Executive Director of Pacific Whiting Conservation Cooperative (representing American Seafoods, Glacier Fish Co. and Trident Seafoods). All three letters were from organizations representing participants in the non-tribal whiting fishery and contained substantive comments. NMFS addresses the summarized comments below. No changes from the proposed rule were made based on comments NMFS received.

Comment 1: A commenter requested NMFS remove the language in the proposed rule that requires NMFS consider Chinook salmon take numbers and bycatch rates in the Pacific Whiting fishery prior to making a reapportionment. The rationale given was that whiting sectors are already mindful of Chinook bycatch, harvesters and processors have implemented significant voluntary measures in recent years to avoid interacting with Chinook. Commenters mentioned that the recently completed Biological Opinion and associated measures includes a new 'hard cap' on Chinook salmon for whiting participants', referring to regulations that close the Pacific whiting fishery after a certain number of Chinook salmon have been caught.

Response: NMFS acknowledges the voluntary measures the Pacific whiting fishery has implemented in recent years to avoid interacting with Chinook salmon, and the continued efforts of the fishery to manage bycatch. Low Chinook salmon bycatch resulting from implementation of voluntary and mandatory measures will be considered prior to reapportionment. NMFS also acknowledges that this is one of several complementary measures that have been put into place as the result of the Biological Opinion, to minimize the impact of the amount or extent of incidental take of ESA-listed Chinook salmon. The terms and conditions of the Biological Opinion are, in part, designed to minimize Chinook salmon interactions with Pacific whiting fishery. Terms and conditions of an ESA biological opinion are non-discretionary, meaning NMFS is obligated under ESA to implement this measure.

The 'hard cap' this comment refers to is a provision implemented (83 FR 63970; December 12, 2018) to give NMFS automatic authority to close

either or both of the whiting and non-whiting sector fisheries if: (1) Either sector catches its guideline limit and the reserve amount; or (2) either sector reaches its guideline limit when the other sector has already taken the reserve amount. The guideline limit for the whiting sector (including tribal and non-tribal vessels in the mothership, catcher/processor (C/P), and Shoreside whiting fleets) is 11,000 Chinook salmon. The guideline limit for the non-whiting sector (including tribal and non-tribal vessels in the Shoreside trawl, fixed gear, and recreational fleets) is 5,500 Chinook salmon. The reserve amount of Chinook is 3,500 fish. The 'hard cap' measure ensures that certain levels of Chinook salmon bycatch are not exceeded. The measure addressed in this final rule has the added purpose of ensuring that non-tribal catch of Pacific whiting that was originally allocated to the Tribal sector does not cause closure of the entire Pacific whiting fishery (tribal and non-tribal sectors), thereby prevent the tribal sector's fishery. Therefore, NMFS is retaining this language in the regulations implementing this final rule.

Comment 2: Three commenters stated that reapportionment is necessary to meet National Standard 1 and achieve optimum yield (OY).

Response: The purpose of the tribal allocation is to facilitate the tribes exercising their treaty right to harvest fish in their usual and accustomed fishing areas in U.S. waters, and NMFS must take the necessary steps to ensure that this opportunity is available to those tribes. In 1994, the United States formally recognized that the four Washington coastal treaty Indian tribes (Makah, Quileute, Hoh, and Quinault) have treaty rights to fish for groundfish, including Pacific whiting, in the Pacific Ocean, and concluded that, in general terms, the quantification of those rights is 50 percent of the harvestable surplus of groundfish that pass through the tribes usual and accustomed fishing areas. These treaty rights are implemented by the Secretary following the procedures outlined in 50 CFR 660.60. The tribal allocation is specific to the tribes, who manage and would optimally harvest all of their allocation. The Council, through the Council process, manages allocations to the non-tribal sectors of the Pacific whiting fishery to achieve optimal yield, in accordance with the National Standards of the Magnuson-Stevens Fishery Conservation and Management Act.

Comment 3: Commenters suggested that NMFS provide for re-apportionment of tribal whiting to specific non-tribal sectors.

Response: This management suggestion is outside of the scope of the measure discussed in the proposed rule but could be achieved through the Council process. In this final rule, revisions to the reapportionment provisions are limited to implementing the non-discretionary terms and conditions of the recently completed ESA Section 7(a)(2) Biological Opinion. NMFS notes that distributing reapportioned tribal whiting to specific non-tribal sectors based on concerns about Chinook salmon bycatch is currently possible, and was done in 2014 (February 10, 2015; 80 FR 7390), based on recommendation by the Council. In that reapportionment action, NMFS distributed reapportioned fish to the MS and C/P sectors but not to the Shorebased IFQ sector, based on voluntary bycatch reduction measures that were taken by the MS and C/P sectors in conjunction with projected higher bycatch rates in the Shorebased IFQ sector, and the fact that the Shorebased IFQ sector had not yet attained their existing allocation.

Comment 4: Commenters said the proposed action leads to uncertainty in the non-tribal fishery about the timing and amount of reapportionment during a given year, which makes it difficult to manage factors such as bycatch and vessel maintenance. One commenter expressed that ''if NMFS poorly manages the tribal allocation by not using the reapportionment process to effectively balance the needs of the tribal and non-tribal fisheries it will cause economic harm within the non-tribal whiting fishery. For example, delaying reapportionment past September 15th hinders the ability of the non-tribal sectors to plan and schedule fishing operations that are necessary to optimally achieve our allocations.''

Response: With this final rule, NMFS issues allocations to the non-tribal participants of the Pacific whiting fishery, and allocations to the tribal participants of the fishery. These amounts are certain for participants in the fishery. It is not the goal of the action, nor would it be appropriate, for NMFS to provide certainty that non-tribal participants will derive benefit from the tribal allocation.

NMFS does not anticipate that this rule will change the timing of reapportionment, because there is no additional data collection or analysis requirement (see response to Comment 9 for a discussion regarding this consideration). NMFS will make every effort to ensure that consideration of Chinook bycatch does not hinder timely reapportionment. Specifically, NMFS continuously tracks information required for considering Chinook bycatch prior to reapportionment as part of managing Chinook bycatch inseason. This information is available in accordance with other components of the ESA Biological Opinion. Therefore, the most up-to-date Chinook bycatch information will be available when NMFS is ready to make the reapportionment decision.

Revisions to the timing of the reapportionment is beyond the scope of the action discussed in the proposed rule. Current regulations, however, do provide NMFS with flexibility in the timing of reapportionment and allow for reapportionment to occur prior to September 15. Based on a review of reapportionment actions in 2012–2018, it does not appear that the timing of the reapportionment impacted operational decisions during that time period. For reference, in 2012 the non-tribal sector caught 24,142 mt more than its initial allocation, of 28,000 mt reapportioned on October 4. In 2013, after a 30,000 mt reallocation on September 18 (sixteen days earlier than in 2012), the non-tribal fishery caught 24,146 mt more than its initial allocation. The sixteen-day earlier reapportionment yielded 4 mt more catch (valued at $1,210 in real dollars). In 2014, a 25,000 mt initial reapportionment on September 12 resulted in only 4,564 mt attained over the initial non-tribal allocation. As discussed in greater detail in response to Comment 12, from 2015–2018, the non-tribal fishery as a whole did not catch its initial allocation, which implies that the timing of reallocations did not likely impact operational decisions during that period. Timing of reapportionments is further addressed below, in response to comment 8.

Comment 5: Commenters expressed views that the proposed action seems punitive to the non-tribal participants in general, and to specific sectors with low Chinook salmon bycatch.

Response: In this final rule, revisions to the reapportionment provisions are limited to implementing the non-discretionary terms and conditions of the recently completed ESA Section 7(a)(2) Biological Opinion. Regulations governing reapportionment give the Secretary discretion, but do not impose an obligation, to reapportion Pacific whiting from the tribal sector of the Pacific whiting fishery to non-tribal sectors. While the non-tribal sectors may receive additional economic benefits via reapportionments from the tribal allocation, it is not punitive to either consider Chinook bycatch before making the reapportionment, or keep allocations in their original sectors. See

the response to Comment 3 for a discussion on distributing reapportioned tribal whiting to specific non-tribal sectors.

Comment 6: Commenters mentioned that the reapportionment is of economic benefit to harvesters.

Response: NMFS agrees that reapportionment is of economic benefit to recipients of additional whiting allocation. This is reflected in the regulatory Impact Review-Initial Regulatory Flexibility Analysis (RIR–IRFA) and Final Regulatory Flexibility Analysis (FRFA).

Comment 7: One commenter expressed concern that the proposed rule made reference to possible impacts to the tribal whiting fishery due to Chinook salmon bycatch taken in the non-tribal fishery, but did not mention anything about Chinook bycatch impacts to the non-tribal fisheries by the tribal fishery.

Response: The impacts to the tribal fishery referenced are specifically associated with the Chinook salmon bycatch that occurs when the non-tribal fishery fishes for Pacific whiting originally allocated to the tribal fishery. Because there is no mechanism to reapportion in the other direction, (from non-tribal sectors to the tribal sector) the second scenario mentioned in the comment (tribal sector causing impacts while fishing for Pacific whiting originally allocated to the non-tribal sectors) cannot happen under current regulations.

Comment 8: A commenter stated: ''Dependent on the interannual variability in the stocks, fishing later in the year can, although not always, increase the probability of encountering salmon. For this reason, the current timeframe for which tribal treaty whiting is reallocated is already later in the year than preferred.'' Accordingly, the commenter requested that reapportionment occur earlier in the year, by August 1st.

Response: The timing of reapportionment in the whiting fishery is outside the scope of action described in the proposed rule, and is addressed further in response to comment 4, above. NMFS is responsible for consulting with the tribes to ensure that reapportionments, should they occur, will not limit tribal harvest opportunities. As explained in the RIR–IRFA, the timing of reapportionment in regulations was intended to allow for the tribal fishery to proceed to a point where it could likely be determined whether the full allocation would be used, while reallocating in time to allow the non-treaty sectors to catch the reallocated fish prior to the onset of winter weather conditions. In some years, the participating tribes may determine prior to September 15 that they will not use a portion of the tribal allocation.

Comment 9: Commenters requested clarity on the metric, guidelines, or inseason analysis NMFS will use to determine reapportionment. One commenter requested detailed criteria describing how Chinook salmon bycatch information will be used to guide the whiting reapportionment process. Another commented that this action increases staff workload to accomplish a task that is already being satisfied with existing management measures, and that the proposed rule will require in-season analysis, increasing the workload of NMFS staff.

Response: NMFS will not conduct additional inseason analysis as a result of this modification to the regulations. NMFS already continuously tracks information required for considering Chinook bycatch prior to reapportionment as part of managing Chinook bycatch inseason. Therefore, the most up-to-date Chinook bycatch information will be available when NMFS is ready to make the reapportionment decision. This modification does not increase the data requirement or workload, but rather requires NMFS to review readily available information, the total number of total Chinook salmon taken by the Pacific whiting fishery and rates of Chinook salmon bycatch in each sector, prior to making a decision about annual reapportionment.

Comment 10: A commenter stated: ''Reapportionment of whiting to non-tribal sectors re-distributes fishing effort from a centralized region in the North to widespread locations along the coastline. Consequently, reapportionment could indirectly provide increased food availability for predators that prey on Northern Chinook stocks. The proposed rule does not acknowledge the conservation benefits that reapportionment provides.''

Response: This action changes neither the existing discretion nor the mechanism NMFS has for the reapportionment. The indirect conservation benefits mentioned in the comment may exist, however they are outside the scope of this action.

Comment 11: Several commenters addressed economic benefits to communities from reapportioning fish and stated that the action prevents economic benefits from accruing, threatens small business, and that the IRFA fails to consider how the discretion provided to NMFS could impact small businesses. Commenters calculated the benefit of reapportionments by multiplying ex-vessel price of Pacific whiting by the amount of historic reapportionments.

Response: The RIR–IRFA indicates allocation to both the tribal and non-tribal sectors provides benefits, in the form of opportunity, to large and small entities across sectors. In response to comments, NMFS clarifies that the value of this additional opportunity is not equivalent to the ex-vessel price multiplied by the amount of reapportioned fish. The U.S. non-tribal whiting fishery catch exceeded initial allocations in 2012–2014 by utilizing reapportioned fish. In 2012 and 2013, the whiting sectors utilized about 24,000 mt of reapportionments of 30,000 and 45,000 mt, respectively. In 2014, the non-tribal fishery utilized about 5,000 mt of a reapportioned 45,000 mt. At annual average shoreside ex-vessel prices ranging from $263 to $352/mt from 2012–2014, the total ex-vessel value of reapportioned fish was $17 million across the three years.

From 2015 to 2018, higher TACs have been correlated with lower attainment, ranging from 58.1–96.5 percent attainment of initial non-tribal allocations. If TACs remain at or near those levels, these lower attainment trends indicate that reapportioned tribal catch is not expected to provide the non-tribal sector additional opportunity over the initial allocations, as cumulatively, 212,714 of initial allocations remained unharvested (53,000 mt per year, on average). While opportunity of reapportioned harvest is generally distributed along fixed allocation percentages in the FMP that are not being reconsidered in the scope of this rule, reapportioned catch has in recent years provided measurable increased revenue to C/P sector, as this sector generally does attain most or all of its initial allocation. All of the permit owners in the C/P sector self-identified in 2019 permit applications as large entities. The proposed rule and corresponding analyses do not include a reconsideration of the allocations either between tribal and non-tribal sectors, or within the non-tribal sector.

Comment 12: A commenter stated: ''In the proposed rule, NMFS states that the re-apportionment process prevents adverse economic impacts—'The reapportioning process allows unharvested tribal allocations of Pacific whiting . . . to be fished by the non-tribal fleets, benefitting both large and small entities. NMFS has prepared an IRFA and is requesting comments on this conclusion.' However, this statement is not supported by any

information in the proposed rule.'' Another commenter stated that they disagreed with the claim that '' 'NMFS believes this proposed rule would not adversely affect small entities', as no evidence for it is provided in the [IRFA].''

Response: NMFS does not claim the reapportionment process prevents adverse economic impacts; rather, the IRFA states '' . . . in 2018 NMFS reapportioned 40,000 mt of the original 77,251 mt tribal allocation. This reapportionment was based on conversations with the tribes and the best information available at the time, which indicated that this amount would not limit tribal harvest opportunities for the remainder of the year. . . . This reapportioning process allows unharvested tribal allocations of Pacific whiting to be fished by the non-tribal fleets, benefitting both large and small entities.''

The benefits of the proposed rule considered in the IRFA include the benefits of the tribal allocation to the tribal sector, and of the non-tribal allocation to each of the commercial sectors in the non-tribal sector. In years when the tribal sector does not use its full allocation and there is a reapportionment to the non-tribal sectors, the reapportioned fish offers additional benefits for small and large entities in the non-tribal sectors. In the IRFA, the benefits from the tribal allocation are assumed to accrue to the tribal sector, with the reapportionment flexibility an additional potential benefit to the non-tribal sector, only in years when the tribal sector does not prosecute the entirety of its allocation. In the IRFA, no portion of the benefits from the tribal allocation are assumed to accrue to the non-tribal sector, which would double-count the value of the benefit of this allocation to the tribal sector.

Classification

The Annual Specifications and Management Measures for the 2019 Tribal and non-Tribal Fisheries for Pacific Whiting, and Consideration of Chinook Salmon Bycatch Before Reapportioning Tribal Pacific Whiting, are issued under the authority of the Magnuson-Stevens Act, and the Whiting Act of 2006. The measures are in accordance with 50 CFR part 660, subparts C through G, the regulations implementing the Pacific Coast Groundfish FMP, and NMFS has determined that this rule is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws.

Pursuant to 5 U.S.C. 553(b)(B) and (d)(3), the NMFS Assistant Administrator finds good cause to waive prior public notice and delay in effectiveness for this final rule, as delaying this rule would be impracticable and contrary to the public interest. The annual harvest specifications for Pacific whiting must be implemented by the start of the primary Pacific whiting season, which begins on May 15, 2019, or the primary Pacific whiting fishery will effectively remain closed.

Every year, NMFS conducts a Pacific whiting stock assessment with participation from U.S. and Canadian scientists. The 2019 stock assessment for Pacific whiting was prepared in February 2019, and included updated total catch, length and age data from the U.S. and Canadian fisheries from 2018, and biomass indices from the 2018 Joint U.S.-Canadian acoustic/midwater trawl surveys. Because of this late availability of the most recent data for the assessment, and the need for time to conduct the treaty process for determining the TAC using the most recent assessment, it would not be possible to allow for notice and comment before the start of the primary Pacific whiting season on May 15.

A delay in implementing the Pacific whiting harvest specifications to allow for notice and comment would be contrary to the public interest because it would require either a shorter primary whiting season or development of a TAC without the most recent data. A shorter season could prevent the tribal and non-tribal fisheries from attaining their 2019 allocations, which would result in unnecessary short-term adverse economic effects for the Pacific whiting fishing vessels and the associated fishing communities. A TAC determined without the most recent data could fail to account for significant fluctuations in the biomass of this relatively short-lived species. To prevent these adverse effects and to allow the Pacific whiting season to commence, it is in the best interest of the public to waive prior notice and comment.

In addition, pursuant to 5 U.S.C. 553(d)(3), the NMFS Assistant Administrator finds good cause to waive the 30-day delay in effectiveness of this final rule. Waiving the 30-day delay in effectiveness will not have a negative impact on any entities, as there are no new compliance requirements or other burdens placed on the fishing community with this rule. Failure to make this final rule effective at the start of the fishing year will undermine the intent of the rule, which is to promote the optimal utilization and conservation of Pacific whiting. Making this rule effective immediately would also serve the best interests of the public because it will allow for the longest possible Pacific whiting fishing season and therefore the best possible economic outcome for those whose livelihoods depend on this fishery. Because the 30-day delay in effectiveness would potentially cause significant financial harm without providing any corresponding benefits, this final rule is effective upon publication in the **Federal Register**.

The Office of Management and Budget has determined that this final rule is not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Final Regulatory Flexibility Analysis

NMFS published a proposed rule on March 15, 2019 (84 FR 9471), for the allocation of the 2019 tribal Pacific whiting fishery and the requirement to consider Chinook salmon bycatch before reapportioning tribal whiting. An IRFA was prepared and summarized in the Classification section of the preamble to the proposed rule. The comment period on the proposed rule ended on April 1, 2019. NMFS received three comment letters on the proposed rule from organizations representing the non-tribal fishery. The Chief Counsel for Advocacy of the SBA did not file any comments on the IRFA or the proposed rule. The description of this action, its purpose, and its legal basis are described in the preamble to the proposed rule and are not repeated here. A final regulatory flexibility analysis (FRFA) was prepared and incorporates the IRFA and response to the public comments, which are summarized in the 'Comments and Responses' section of this final rule. NMFS also prepared a Regulatory Impact Review (RIR) for this action. A copy of the RIR/FRFA is available from NMFS (see Electronic Access). A summary of the FRFA, per the requirements of 5 U.S.C. 604 follows.

NMFS considered two alternatives for this action: The ''No-Action'' and the ''Action.'' The tribal allocation is based primarily on the requests of the tribes. These requests reflect the level of participation in the fishery that will allow them to exercise their treaty right to fish for Pacific whiting. Under the Action alternative, NMFS sets the tribal allocation percentage at 17.5 percent, as requested by the tribes. This yields a tribal allocation of 77,251 mt for 2019. Consideration of a percentage lower

than the tribal request of 17.5 percent is not appropriate in this instance. As a matter of policy, NMFS has historically supported the harvest levels requested by the tribes. Based on the information available to NMFS, the tribal request is within their tribal treaty rights. A higher percentage would arguably also be within the scope of the treaty right. However, a higher percentage would unnecessarily limit the non-tribal fishery. NMFS also announces the 2019 U.S. Total Allowable Catch (TAC) of 441,433 metric tons of Pacific whiting, establishes a set-aside for research and bycatch of 1,500 mt, and 362,682 mt for the non-tribal fishery for 2019. Under the action alternative, NMFS requires the consideration of the number and bycatch rate by sector of Chinook salmon bycatch before reapportioning tribal whiting, as required by the 2017 ESA Biological Opinion. Consideration of other factors such as timing, location, and genetics of bycatch would not be feasible as an inseason automatic action, which is the mechanism by which these reapportionments occur.

Under the no-action alternative, NMFS would not have made allocations, which would not fulfill NMFS' responsibility to manage the fishery. This alternative was considered, but the regulatory framework provides for a tribal allocation, research and bycatch set-aside, and harvest guideline on an annual basis only. Therefore, the no-action alternative would result in no allocation of Pacific whiting to the tribal sector in 2019, which would be inconsistent with NMFS' responsibility to manage the fishery consistent with the tribes' treaty rights. Given that there is a tribal request for allocation and the Council recommended a research and bycatch set-aside in 2019, this alternative received no further consideration. Under the no-action alternative, NMFS would not consider Chinook salmon bycatch, as required by the Biological Opinion. While the consideration of Chinook bycatch may negatively impact both large and small entities in the event of a high bycatch year, there are no alternatives identified that would be consistent with the applicable ESA requirements that would also minimize any significant economic impact of the proposed rule on small entities.

RFA-Determination of a Significant Impact

This rule is similar to previous rule makings concerning whiting. Against an internationally set TAC, this rule concerns the amount of the US TAC that should be allocated to the tribal fishery, establishes a set-aside for research and bycatch of 1,500 mt, announces Pacific whiting allocations of 77,251 mt to the tribal and 362,683 mt for the non-tribal fishery for 2019, and requires NMFS to consider bycatch of Chinook salmon before reapportioning tribal whiting. The tribal allocation is based primarily on the requests of the tribes. These requests reflect the level of participation in the fishery that will allow them to exercise their treaty right to fish for whiting. Tribes are considered small entities. The reapportioning process allows unharvested tribal allocations of whiting, fished by small entities, to be fished by the non-tribal fleets, benefitting both large and small entities. NMFS has determined this rule will not adversely affect small entities and did not receive any comments in response to the IRFA to alter this conclusion.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

There are no reporting or recordkeeping requirements associated with this final rule. No federal rules have been identified that duplicate, overlap, or conflict with this action.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this and the related 2019–2020 Biennial Specifications and Management Measures for the Pacific Coast Groundfish Fishery (83 FR 63970) rulemaking process, a small entity compliance guide was sent to stakeholders, and copies of the final rule and guides (*i.e.,* information bulletins) are available from NMFS at the following website: *http://www.westcoast.fisheries.noaa.gov/fisheries/management/whiting/pacific_whiting.html.*

Consultation and Coordination With Indian Tribal Governments

Pursuant to Executive Order 13175, this final rule was developed after meaningful collaboration with tribal officials from the area covered by the FMP. Consistent with the Magnuson-Stevens Act at 16 U.S.C. 1852(b)(5), one of the voting members of the Pacific Council is a representative of an Indian tribe with federally recognized fishing rights from the area of the Council's jurisdiction. In addition, NMFS has coordinated specifically with the tribes interested in the whiting fishery regarding the issues addressed by this final rule.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Indian Fisheries.

Dated: May 7, 2019.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.50, revise paragraph (f)(4) to read as follows:

§ 660.50 Pacific Coast treaty Indian fisheries.

* * * * *

(f) * * *

(4) *Pacific whiting.* The tribal allocation for 2019 is 77,251 mt.

* * * * *

3. Tables 1a and 1b to part 660, subpart C, are revised to read as follows:

TABLE 1A TO PART 660, SUBPART C—2019, SPECIFICATIONS OF OFL, ABC, ACL, ACT AND FISHERY HG

[Weights in metric tons]

Stocks/stock complexes	Area	OFL	ABC	ACL [a/]	Fishery HG [b/]
COWCOD [c]	S of 40° 10′ N lat	74	67	10	8
COWCOD	(Conception)	61	56	NA	NA
COWCOD	(Monterey)	13	11	NA	NA
YELLOWEYE ROCKFISH [d]	Coastwide	82	74	48	42

TABLE 1A TO PART 660, SUBPART C—2019, SPECIFICATIONS OF OFL, ABC, ACL, ACT AND FISHERY HG—Continued

[Weights in metric tons]

Stocks/stock complexes	Area	OFL	ABC	ACL [a/]	Fishery HG [b/]
Arrowtooth Flounder [e]	Coastwide	18,696	15,574	15,574	13,479
Big Skate [f]	Coastwide	541	494	494	452
Black Rockfish [g]	California (S of 42° N lat.)	344	329	329	328
Black Rockfish [h]	Washington (N of 46° 16′ N lat.)	312	298	298	280
Bocaccio [i]	S of 40° 10′ N lat	2,194	2,097	2,097	2,051
Cabezon [j]	California (S of 42° N lat.)	154	147	147	147
California Scorpionfish [k]	S of 34° 27′ N lat	337	313	313	311
Canary Rockfish [l]	Coastwide	1,517	1,450	1,450	1,383
Chilipepper Rockfish [m]	S of 40° 10′ N lat.	2,652	2,536	2,536	2,451
Darkblotched Rockfish [n]	Coastwide	800	765	765	731
Dover Sole [o]	Coastwide	91,102	87,094	50,000	48,404
English Sole [p]	Coastwide	11,052	10,090	10,090	9,874
Lingcod [q]	N of 40° 10′ N lat	5,110	4,885	4,871	4,593
Lingcod [r]	S of 40° 10′ N lat	1,143	1,093	1,039	1,028
Longnose Skate [s]	Coastwide	2,499	2,389	2,000	1,852
Longspine Thornyhead [t]	N of 34°27′ N lat	4,112	3,425	2,603	2,553
Longspine Thornyhead [u]	S of 34° 27′ N lat			822	821
Pacific Cod [v]	Coastwide	3,200	2,221	1,600	1,094
Pacific Whiting [w]	Coastwide	725,593	[w/]	[w/]	362,682
Pacific Ocean Perch [x]	N of 40° 10′ N lat	4,753	4,340	4,340	4,318
Petrale Sole [y]	Coastwide	3,042	2,908	2,908	2,587
Sablefish [z]	N of 36° N lat	8,489	7,750	5,606	See Table 1c
Sablefish [aa]	S of 36° N lat	.....	.....	1,990	1,986
Shortbelly Rockfish [bb]	Coastwide	6,950	5,789	500	483
Shortspine Thornyhead [cc]	N of 34° 27′ N lat	3,089	2,573	1,683	1,618
Shortspine Thornyhead [dd]	S of 34° 27′ N lat			890	889
Spiny Dogfish [ee]	Coastwide	2,486	2,071	2,071	1,738
Splitnose Rockfish [ff]	S of 40° 10′ N lat	1,831	1,750	1,750	1,733
Starry Flounder [gg]	Coastwide	652	452	452	433
Widow Rockfish [hh]	Coastwide	12,375	11,831	11,831	11,583
Yellowtail Rockfish [ii]	N of 40° 10′ N lat	6,568	6,279	6,279	5,234
Black Rockfish/Blue Rockfish/Deacon Rockfish [jj].	Oregon (Between 46° 16′ N lat. and 42° N lat.).	677	617	617	616
Cabezon/Kelp Greenling [kk]	Oregon (Between 46° 16′ N lat. and 42° N lat.).	230	218	218	218
Cabezon/Kelp Greenling [ll]	Washington (N of 46° 16′ N lat.)	13	11	11	11
Nearshore Rockfish [mm]	N of 40° 10prime; N lat	91	81	81	79
Shelf Rockfish [nn]	N of 40° 10prime; N lat	2,309	2,054	2,054	1,977
Slope Rockfish [oo]	N of 40° 10prime; N lat	1,887	1,746	1,746	1,665
Nearshore Rockfish [pp]	S of 40° 10′ N lat	1,300	1,145	1,142	1,138
Shelf Rockfish [qq]	S of 40° 10′ N lat	1,919	1,625	1,625	1,546
Slope Rockfish [rr]	S of 40° 10′ N lat	856	744	744	724
Other Flatfish [ss]	Coastwide	8,750	6,498	6,498	6,249
Other Fish [tt]	Coastwide	286	239	239	230

[a] Annual catch limits (ACLs), annual catch targets (ACTs) and harvest guidelines (HGs) are specified as total catch values.

[b] Fishery HGs means the HG or quota after subtracting Pacific Coast treaty Indian tribes allocations and projected catch, projected research catch, deductions for fishing mortality in non-groundfish fisheries, and deductions for EFPs from the ACL or ACT.

[c] Cowcod south of 40° 10′ N lat. 2 mt is deducted from the ACL to EFP fishing (less than 0.1 mt) and research activity (2 mt), resulting in a fishery HG of 8 mt. Any additional mortality in research activities will be deducted from the ACL. A single ACT of 6 mt is being set for the Conception and Monterey areas combined.

[d] Yelloweye rockfish. The 48 mt ACL is based on the current rebuilding plan with a target year to rebuild of 2029 and an SPR harvest rate of 65 percent. 6.1 mt is deducted from the ACL to accommodate the Tribal fishery (2.3 mt), the incidental open access fishery (0.62 mt), EFP catch (0.24 mt) and research catch (2.92 mt), resulting in a fishery HG of 42 mt. The non-trawl HG is 38.6 mt. The non-nearshore HG is 2.0 mt and the nearshore HG is 6.0 mt. Recreational HGs are: 10 mt (Washington); 8.9 mt (Oregon); and 11.6 mt (California). In addition, there are the following ACTs: Non-nearshore (1.6 mt), nearshore (4.7 mt), Washington recreational (7.8 mt), Oregon recreational (7.0 mt), and California recreational (9.1 mt).

[e] Arrowtooth flounder. 2,094.9 mt is deducted from the ACL to accommodate the Tribal fishery (2,041 mt), the incidental open access fishery (40.8 mt), EFP fishing (0.1 mt), and research catch (13 mt), resulting in a fishery HG of 13,479 mt.

[f] Big skate. 41.9 mt is deducted from the ACL to accommodate the Tribal fishery (15 mt), the incidental open access fishery (21.3 mt), EFP fishing (0.1 mt), and research catch (5.5 mt), resulting in a fishery HG of 452 mt.

[g] Black rockfish (California). 1.3 mt is deducted from the ACL to accommodate EFP fishing (1.0 mt) and incidental open access fishery (0.3 mt), resulting in a fishery HG of 328 mt.

[h] Black rockfish (Washington). 18.1 mt is deducted from the ACL to accommodate the Tribal fishery (18 mt) and research catch (0.1 mt), resulting in a fishery HG of 280 mt.

[i] Bocaccio south of 40° 10′; N lat. The stock is managed with stock-pecific harvest specifications south of 40° 10′; N lat. and within the Minor Shelf Rockfish complex north of 40° 10′; N lat. 46.1 mt is deducted from the ACL to accommodate the incidental open access fishery (0.5 mt), EFP catch (40 mt) and research catch (5.6 mt), resulting in a fishery HG of 2,051 mt. The California recreational fishery south of 40° 10′; N lat has an HG of 863.4 mt.

[j] Cabezon (California). 0.3 mt is deducted from the ACL to accommodate the incidental open access fishery, resulting in a fishery HG of 147 mt.

[k] California scorpionfish south of 34° 27′ N lat. 2.4 mt is deducted from the ACL to accommodate the incidental open access fishery (2.2 mt) and research catch (0.2 mt), resulting in a fishery HG of 311 mt.

[l] Canary rockfish. 67.1 mt is deducted from the ACL to accommodate the Tribal fishery (50 mt), the incidental open access fishery (1.3 mt), EFP catch (8 mt), and research catch (7.8 mt), resulting in a fishery HG of 1,383 mt. Recreational HGs are: 47.1 mt (Washington); 70.7 mt (Oregon); and 127.3 mt (California).

[m] Chilipepper rockfish south of 40° 10′; N lat. Chilipepper are managed with stock-specific harvest specifications south of 40° 10′N lat. and within the Minor Shelf Rockfish complex north of 40° 10′ N lat. 84.9 mt is deducted from the ACL to accommodate the incidental open access fishery (11.5 mt), EFP fishing (60 mt), and research catch (13.4 mt), resulting in a fishery HG of 2,451 mt.

[n] Darkblotched rockfish. 33.8 mt is deducted from the ACL to accommodate the Tribal fishery (0.2 mt), the incidental open access fishery (24.5 mt), EFP catch (0.6 mt), and research catch (8.5 mt) resulting in a fishery HG of 731 mt.

[o] Dover sole. 1,595.6 mt is deducted from the ACL to accommodate the Tribal fishery (1,497 mt), the incidental open access fishery (49.3 mt), EFP fishing (0.1 mt), and research catch (49.2 mt), resulting in a fishery HG of 48,404 mt.

[p] English sole. 216.2 mt is deducted from the ACL to accommodate the Tribal fishery (200 mt), the incidental open access fishery (8.1 mt), EFP fishing (0.1 mt), and research catch (8 mt), resulting in a fishery HG of 9,874 mt.

[q] Lingcod north of 40° 10′; N lat. 278 mt is deducted from the ACL for the Tribal fishery (250 mt), the incidental open access fishery (9.8 mt), EFP catch (1.6 mt) and research catch (16.6 mt), resulting in a fishery HG of 4,593 mt.

[r] Lingcod south of 40° 10′; N lat. 11.3 mt is deducted from the ACL to accommodate the incidental open access fishery (8.1 mt) and research catch (3.2 mt), resulting in a fishery HG of 1,028 mt.

[s] Longnose skate. 148.3 mt is deducted from the ACL to accommodate the Tribal fishery (130 mt), incidental open access fishery (5.7 mt), EFP catch (0.1 mt), and research catch (12.5 mt), resulting in a fishery HG of 1,852 mt.

[t] Longspine thornyhead north of 34° 27′ N lat. 50.4 mt is deducted from the ACL to accommodate the Tribal fishery (30 mt), the incidental open access fishery (6.2 mt), and research catch (14.2 mt), resulting in a fishery HG of 2,553 mt.

[u] Longspine thornyhead south of 34° 27′ N lat. 1.4 mt is deducted from the ACL to accommodate research catch, resulting in a fishery HG of 821 mt.

[v] Pacific cod. 506.2 mt is deducted from the ACL to accommodate the Tribal fishery (500 mt), research catch (5.5 mt), EFP fishing (0.1 mt), and the incidental open access fishery (0.6 mt), resulting in a fishery HG of 1,094 mt.

[w] Pacific whiting. The coastwide stock assessment was published in 2019 and estimated the spawning stock to be at 64 percent of its unfished biomasS The 2019 OFL of 725,593 mt is based on the 2019 assessment with an F40% FMSY proxy. The 2019 coastwide, unadjusted Total Allowable Catch (TAC) of 519,834 mt is based on the 2019 stock assessment. The U.S. TAC is 73.88 percent of the coastwide unadjusted TAC. Up to 15 percent of each party's unadjusted 2018 TAC (57,380 mt for the U.S.) is added to each party's 2019 unadjusted TAC, resulting in a U.S. adjusted 2019 TAC of 441,433 mt. From the adjusted U.S. TAC, 77,251 mt is deducted to accommodate the Tribal fishery, and 1,500 mt is deducted to accommodate research and bycatch in other fisheries, resulting in a 2019 fishery HG of 362,682 mt. The TAC for Pacific whiting is established under the provisions of the Agreement with Canada on Pacific Hake/Whiting and the Pacific Whiting Act of 2006, 16 U.S.C. 7001–7010, and the international exception applies. Therefore, no ABC or ACL values are provided for Pacific whiting.

[x] Pacific ocean perch north of 40° 10′; N lat. 22.4 mt is deducted from the ACL to accommodate the Tribal fishery (9.2 mt), the incidental open access fishery (10 mt), EFP fishing (0.1 mt), and research catch (3.1 mt) resulting in a fishery HG of 4,318 mt.

[y] Petrale sole. 320.6 mt is deducted from the ACL to accommodate the Tribal fishery (290 mt), the incidental open access fishery (6.4 mt), EFP catch (0.1 mt), and research catch (24.1 mt), resulting in a fishery HG of 2,587 mt.

[z] Sablefish north of 36° N lat. The 40–10 adjustment is applied to the ABC to derive a coastwide ACL value because the stock is in the precautionary zone. This coastwide ACL value is not specified in regulations. The coastwide ACL value is apportioned north and south of 36° N lat., using the 2003–2014 average estimated swept area biomass from the NMFS NWFSC trawl survey, with 73.8 percent apportioned north of 36° N lat. and 26.2 percent apportioned south of 36° N lat. The northern ACL is 5,606 mt and is reduced by 561 mt for the Tribal allocation (10 percent of the ACL north of 36° N lat.). The 561 mt Tribal allocation is reduced by 1.5 percent to account for discard mortality. Detailed sablefish allocations are shown in Table 1c.

[aa] Sablefish south of 36° N lat. The ACL for the area south of 36° N lat. is 1,990 mt (26.2 percent of the calculated coastwide ACL value). 4.2 mt is deducted from the ACL to accommodate the incidental open access fishery (1.8 mt) and research catch (2.4 mt), resulting in a fishery HG of 1,986 mt.

[bb] Shortbelly rockfish. 17.2 mt is deducted from the ACL to accommodate the incidental open access fishery (8.9 mt), EFP catch (0.1 mt), and research catch (8.2 mt), resulting in a fishery HG of 483 mt.

[cc] Shortspine thornyhead north of 34° 27′ N lat. 65.3 mt is deducted from the ACL to accommodate the Tribal fishery (50 mt), the incidental open access fishery (4.7 mt), EFP catch (0.1 mt), and research catch (10.5 mt), resulting in a fishery HG of 1,618 mt for the area north of 34° 27′ N lat.

[dd] Shortspine thornyhead south of 34° 27′ N lat. 1.2 mt is deducted from the ACL to accommodate the incidental open access fishery (0.5 mt) and research catch (0.7 mt), resulting in a fishery HG of 889 mt for the area south of 34° 27′ N lat.

[ee] Spiny dogfish. 333 mt is deducted from the ACL to accommodate the Tribal fishery (275 mt), the incidental open access fishery (22.6 mt), EFP catch (1.1 mt), and research catch (34.3 mt), resulting in a fishery HG of 1,738 mt.

[ff] Splitnose rockfish south of 40° 10′; N lat. Splitnose rockfish in the north is managed in the Slope Rockfish complex and with stock-specific harvest specifications south of 40°10′ N lat. 16.6 mt is deducted from the ACL to accommodate the incidental open access fishery (5.8 mt), research catch (9.3 mt) and EFP catch (1.5 mt), resulting in a fishery HG of 1,733 mt.

[gg] Starry flounder. 18.8 mt is deducted from the ACL to accommodate the Tribal fishery (2 mt), EFP catch (0.1 mt), research catch (0.6 mt), and the incidental open access fishery (16.1 mt), resulting in a fishery HG of 433 mt.

[hh] Widow rockfish. 248.4 mt is deducted from the ACL to accommodate the Tribal fishery (200 mt), the incidental open access fishery (3.1 mt), EFP catch (28 mt) and research catch (17.3 mt), resulting in a fishery HG of 11,583 mt.

[ii] Yellowtail rockfish north of 40° 10′; N lat. 1,045.1 mt is deducted from the ACL to accommodate the Tribal fishery (1,000 mt), the incidental open access fishery (4.5 mt), EFP catch (20 mt) and research catch (20.6 mt), resulting in a fishery HG of 5,234 mt.

[jj] Black rockfish/Blue rockfish/Deacon rockfish (Oregon). 1.2 mt is deducted from the ACL to accommodate the incidental open access fishery (0.3 mt) and EFP catch (0.9 mt), resulting in a fishery HG of 616 mt.

[kk] Cabezon/kelp greenling (Oregon). 0.2 mt is deducted from the ACL to accommodate EFP catch, resulting in a fishery HG of 218 mt.

[ll] Cabezon/kelp greenling (Washington). There are no deductions from the ACL so the fishery HG is equal to the ACL of 11 mt.

[mm] Nearshore Rockfish north of 40° 10′; N lat. 2.8 mt is deducted from the ACL to accommodate the Tribal fishery (1.5 mt), EFP fishing (0.1 mt), research catch (0.3 mt) and the incidental open access fishery (0.9 mt), resulting in a fishery HG of 79 mt.

[nn] Shelf Rockfish north of 40° 10′; N lat. 76.9 mt is deducted from the ACL to accommodate the Tribal fishery (30 mt), the incidental open access fishery (17.7 mt), EFP catch (4.5 mt), and research catch (24.7 mt), resulting in a fishery HG of 1,977 mt.

[oo] Slope Rockfish north of 40° 10′; N lat. 80.8 mt is deducted from the ACL to accommodate the Tribal fishery (36 mt), the incidental open access fishery (21.7 mt), EFP catch (1.5 mt), and research catch (21.6 mt), resulting in a fishery HG of 1,665 mt.

[pp] Nearshore Rockfish south of 40° 10′; N lat. 4.1 mt is deducted from the ACL to accommodate the incidental open access fishery (1.4 mt) and research catch (2.7 mt), resulting in a fishery HG of 1,138 mt.

[qq] Shelf Rockfish south of 40° 10′; N lat. 79.1 mt is deducted from the ACL to accommodate the incidental open access fishery (4.6 mt), EFP catch (60 mt), and research catch (14.5 mt), resulting in a fishery HG of 1,546 mt.

[rr] Slope Rockfish south of 40° 10′; N lat. 20.2 mt is deducted from the ACL to accommodate the incidental open access fishery (16.9 mt), EFP catch (1 mt), and research catch (2.3 mt), resulting in a fishery HG of 724 mt. Blackgill rockfish has a stock-specific HG for the entire groundfish fishery south of 40° 10′; N lat. set equal to the speciesprime; contribution to the 40° 10′; adjusted ACL. Harvest of blackgill rockfish in all groundfish fisheries south of 40° 10′; N lat. counts against this HG of 159 mt.

[ss] Other Flatfish. The Other Flatfish complex is comprised of flatfish species managed in the PCGFMP that are not managed with stock-specific OFLs/ABCs/ACLs. Most of the species in the Other Flatfish complex are unassessed and include: Butter sole, curlfin sole, flathead sole, Pacific sanddab, rock sole, sand sole, and rex sole. 249.5 mt is deducted from the ACL to accommodate the Tribal fishery (60 mt), the incidental open access fishery (161.6 mt), EFP fishing (0.1 mt), and research catch (27.8 mt), resulting in a fishery HG of 6,249 mt.

[tt] Other Fish. The Other Fish complex is comprised of kelp greenling off California and leopard shark coastwide. 8.9 mt is deducted from the ACL to accommodate the incidental open access fishery (8.8 mt) and research catch (0.1 mt), resulting in a fishery HG of 230 mt.

TABLE 1b TO PART 660, SUBPART C—2019, ALLOCATIONS BY SPECIES OR SPECIES GROUP

[Weight in metric tons]

Stocks/stock complexes	Area	Fishery HG or ACT [a b]	Trawl		Non-trawl	
			%	Mt	%	Mt
Arrowtooth flounder	Coastwide	13,479.1	95	12,805.1	5	674.0
Big skate [a]	Coastwide	452.1	95	429.5	5	22.6
Bocaccio [a]	S of 40°10′ N lat	2,050.9	39	800.7	61	1,250.2
Canary rockfish [a d]	Coastwide	1,382.9	72	999.6	28	383.3
Chilipepper	S of 40°10′ N lat	2,451.1	75	1,838.3	25	612.8
COWCOD [a b]	S of 40°10′ N lat	6.0	36	2.2	64	3.8
Darkblotched rockfish [c]	Coastwide	731.2	95	694.6	5	36.6
Dover sole	Coastwide	48,404.4	95	45,984.2	5	2,420.2
English sole	Coastwide	9,873.8	95	9,380.1	5	493.7
Lingcod	N of 40′10° N lat	4,593.0	45	2,066.9	55	2,526.2
Lingcod	S of 40′10° N lat	1,027.7	45	462.5	55	565.2
Longnose skate [a]	Coastwide	1,851.7	90	1,666.5	10	185.2
Longspine thornyhead	N of 34°27′ N lat	2,552.6	95	2,425.0	5	127.6
Pacific cod	Coastwide	1,093.8	95	1,039.1	5	54.7
Pacific whiting [g]	Coastwide	362,682.0	100	362,682.0	0	0.0
Pacific ocean perch [e]	N of 40°10′ N lat	4,317.6	95	4,101.7	5	215.9
Petrale sole	Coastwide	2,587.4	95	2,458.0	5	129.4
Sablefish	N of 36° N lat	NA	See Table 1c			
Sablefish	S of 36° N lat	1,985.8	42	834.0	58	1,151.8
Shortspine thornyhead	N of 34°27′ N lat	1,617.7	95	1,536.8	5	80.9
Shortspine thornyhead	S of 34°27′ N lat	888.8	NA	50.0	NA	838.8
Splitnose rockfish	S of 40°10′ N lat	1,733.4	95	1,646.7	5	86.7
Starry flounder	Coastwide	433.2	50	216.6	50	216.6
Widow rockfish [f]	Coastwide	11,582.6	91	10,540.2	9	1,042.4
YELLOWEYE ROCKFISH	Coastwide	41.9	8	3.4	92	38.6
Yellowtail rockfish	N of 40°10′ N lat	4,951.9	88	4,357.7	12	594.2
Minor Shelf Rockfish North [a]	N of 40°10′ N lat	1,977.1	60.2	1,190.2	39.8	786.9
Minor Shelf Rockfish South [a].	S of 40°10′ N lat	1,545.9	12.2	188.6	87.8	1,357.3
Minor Slope Rockfish North	N of 40°10′ N lat	1,665.2	81	1,348.8	19	316.4
Minor Slope Rockfish South	S of 40°10′ N lat	723.8	63	456.0	37	267.8
Other Flatfish	Coastwide	6,248.5	90	5,623.7	10	624.9

[a] Allocations decided through the biennial specification process.

[b] The cowcod fishery harvest guideline is further reduced to an ACT of 6.0 mt.

[c] Consistent with regulations at § 660.55(c), 9 percent (62.5 mt) of the total trawl allocation for darkblotched rockfish is allocated to the Pacific whiting fishery, as follows: 26.3 mt for the Shorebased IFQ Program, 15.0 mt for the MS sector, and 21.3 mt for the C/P sector. The tonnage calculated here for the Pacific whiting IFQ fishery contributes to the total shorebased trawl allocation, which is found at § 660.140(d)(1)(ii)(D).

[d] 46 mt of the total trawl allocation of canary rockfish is allocated to the MS and C/P sectors, as follows: 30 mt for the MS sector, and 16 mt for the C/P sector.

[e] Consistent with regulations at § 660.55(c), 17 percent (697.3 mt) of the total trawl allocation for Pacific ocean perch is allocated to the Pacific whiting fishery, as follows: 292.9 mt for the Shorebased IFQ Program, 167.4 mt for the MS sector, and 237.1 mt for the C/P sector. The tonnage calculated here for the Pacific whiting IFQ fishery contributes to the total shorebased trawl allocation, which is found at § 660.140(d)(1)(ii)(D).

[f] Consistent with regulations at § 660.55(c), 10 percent (1,054 mt) of the total trawl allocation for widow rockfish is allocated to the whiting fisheries, as follows: 442.7 mt for the shorebased IFQ fishery, 253 mt for the mothership fishery, and 358.4 mt for the catcher/processor fishery. The tonnage calculated here for the whiting portion of the shorebased IFQ fishery contributes to the total shorebased trawl allocation, which is found at § 660.140(d)(1)(ii)(D).

[g] Consistent with regulations at § 660.55(i)(2), the commercial harvest guideline for Pacific whiting is allocated as follows: 34 percent (123,312 mt) for the C/P Coop Program; 24 percent (87,044 mt) for the MS Coop Program; and 42 percent (152,326.5 mt) for the Shorebased IFQ Program. No more than 5 percent of the Shorebased IFQ Program allocation (7,616 mt) may be taken and retained south of 42° N lat before the start of the primary Pacific whiting season north of 42° N lat.

■ 4. In § 660.140, revise paragraph (d)(1)(ii)(D) to read as follows:

§ 660.140 Shorebased IFQ Program.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(D) For the trawl fishery, NMFS will issue QP based on the following shorebased trawl allocations:

TABLE 1 TO PARAGRAPH (d)(1)(ii)(D)

IFQ species	Area	2019 Shorebased trawl allocation (mt)	2020 Shorebased trawl allocation (mt)
Arrowtooth flounder	Coastwide	12,735.1	10,052.3
Bocaccio	South of 40°10′ N lat	800.7	767.1
Canary rockfish	Coastwide	953.6	894.3

TABLE 1 TO PARAGRAPH (d)(1)(ii)(D)—Continued

IFQ species	Area	2019 Shorebased trawl allocation (mt)	2020 Shorebased trawl allocation (mt)
Chilipepper	South of 40°10′ N lat	1,838.3	1,743.8
COWCOD	South of 40°10′ N lat	2.2	2.2
Darkblotched rockfish	Coastwide	658.4	703.4
Dover sole	Coastwide	45,979.2	45,979.2
English sole	Coastwide	9,375.1	9,417.9
Lingcod	North of 40°10′ N lat	2,051.9	1,903.4
Lingcod	South of 40°10′ N lat	462.5	386.0
Longspine thornyhead	North of 34°27′ N lat	2,420.0	2,293.6
Minor Shelf Rockfish complex	North of 40°10′ N lat	1,155.2	1,151.6
Minor Shelf Rockfish complex	South of 40°10′ N lat	188.6	188.6
Minor Slope Rockfish complex	North of 40°10′ N lat	1,248.8	1,237.5
Minor Slope Rockfish complex	South of 40°10′ N lat	456.0	455.4
Other Flatfish complex	Coastwide	5,603.7	5,192.4
Pacific cod	Coastwide	1,034.1	1,034.1
Pacific ocean perch	North of 40°10′ N lat	3,697.3	3,602.2
Pacific whiting	Coastwide	152,326.5	TBD
Petrale sole	Coastwide	2,453.0	2,393.2
Sablefish	North of 36° N lat	2,581.3	2,636.8
Sablefish	South of 36° N lat	834.0	851.7
Shortspine thornyhead	North of 34°27′ N lat	1,506.8	1,493.5
Shortspine thornyhead	South of 34°27′ N lat	50.0	50.0
Splitnose rockfish	South of 40°10′ N lat	1,646.7	1,628.7
Starry flounder	Coastwide	211.6	211.6
Widow rockfish	Coastwide	9,928.8	9,387.1
YELLOWEYE ROCKFISH	Coastwide	3.4	3.4
Yellowtail rockfish	North of 40°10′ N lat	4,305.8	4,048.0

* * * * *

[FR Doc. 2019–09661 Filed 5–9–19; 8:45 am]

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Proposed Rules

Federal Register
Vol. 84, No. 91
Friday, May 10, 2019

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 HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR–6124–P–01]

RIN 2501–AD89

Housing and Community Development Act of 1980: Verification of Eligible Status

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would make two changes to HUD's regulations implementing section 214 of the Housing and Community Development Act of 1980, as amended (Section 214). Section 214 prohibits the Secretary of HUD from making financial assistance available to persons other than United States citizens or certain categories of eligible noncitizens in HUD's public and specified assisted housing programs. The proposed rule would require the verification of the eligible immigration status of all recipients of assistance under a covered program who are under the age of 62. As a result, the proposed rule would make prorated assistance a temporary condition pending verification of eligible status, as opposed to under the current regulation where it could continue indefinitely. The proposed rule would also specify that individuals who are not in eligible immigration status may not serve as the leaseholder, even as part of a mixed family whose assistance is prorated based on the percentage of members with eligible status. HUD believes the amendments will bring its regulations into greater alignment with the wording and purpose of Section 214.

DATES: *Comment Due Date:* July 9, 2019.

ADDRESSES: Interested persons are invited to submit comments to the Office of the General Counsel, Rules Docket Clerk, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10276, Washington, DC 20410–0001. Communications should refer to the above docket number and title and should contain the information specified in the ''Request for Comments'' section. There are two methods for submitting public comments.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at all Federal agencies, however, submission of comments by mail often results in delayed delivery. To ensure timely receipt of comments, HUD recommends that comments by mail be submitted at least 2 weeks in advance of the public comment deadline.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimiled Comments. Facsimiled (faxed) comments are not acceptable.

Public Inspection of Comments. All comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Copies of all comments submitted are available for inspection and downloading at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: John Gibbs, Senior Advisor, Office of the Secretary, Department of Housing and Urban Development, 451 7th Street, SW, Room 10282, Washington, DC 20410; telephone number (202) 402–4445 (this is not a toll-free number). Individuals with hearing or speech impediments may access this number via TTY by calling the Federal Relay, during working hours, at 1 (800) 877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Section 214 of the Housing and Community Development Act of 1980

Section 214 of the Housing and Community Development Act of 1980, as amended (42 U.S.C. 1436a) (Section 214) prohibits HUD from making certain financial assistance available to persons other than United States citizens or specified categories of eligible noncitizens. The Section 214 requirements apply to financial assistance provided under the following HUD programs (collectively referred to as Section 214 covered programs):

1. Section 235 of the National Housing Act (12 U.S.C. 1715z) (the Section 235 Program);
2. Section 236 of the National Housing Act (12 U.S.C. 1715z–1) (tenants paying below market rent only) (the Section 236 Program);
3. Section 101 of the Housing and Urban Development Act of 1965 (12 U.S.C. 1701s) (the Rent Supplement Program); and
4. The United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*) which covers: HUD's Public Housing programs, the Section 8 Housing Assistance programs, and the Housing Development Grant programs (with respect to low-income units only).[1]

Section 214 states that the ''Secretary [of HUD] may not provide . . . assistance for the benefit of . . . [an] individual before documentation [of eligible immigration status] is presented and verified.''[2] This is consistent with the statute's stated goal of ensuring that HUD's limited financial resources be used to aid families lawfully present in the United States, encompassing U.S. citizens and nationals, as well as

[1] 42 U.S.C. 1436a(b). Additional limitations on noncitizen eligibility are also found in the Personal Responsibility and Work Opportunity Act of 1996, 8 U.S.C. 1611(b)(1)(E).

[2] 42 U.S.C. 1436a(d)(2).

noncitizens with eligible immigration status as set forth in HUD regulations.[3] However, Section 214 also contains several provisions to mitigate the potential impacts on the elderly and families. The Housing and Community Development Act of 1987[4] (1987 HCD Act) amended Section 214 to exempt individuals 62 years of age or older from the immigration status verification requirements.[5] The 1987 HCD Act also amended Section 214 to authorize ''preservation assistance'' to prevent the separation of families already receiving assistance on ''the date of enactment of the'' 1987 HCD Act (*i.e.,* February 5, 1988). Specifically, Section 214 authorizes the continuation of assistance to such a family if ''necessary to avoid the division of the family'' and the head of household or spouse has eligible immigration status.[6] Assistance to such families, however, ''may be provided only on a prorated basis, under which the amount of financial assistance is based on the percentage of the total number of [eligible] members.''[7] Section 214 also authorized the temporary deferral of termination of assistance for families receiving assistance on February 5, 1988, but who were ineligible for continued assistance on a prorated basis ''to permit the orderly transition of the individual and any family members involved to other affordable housing.''[8]

II. HUD's Regulations Implementing Section 214

HUD's original regulations implementing Section 214 were promulgated by final rule published on March 20, 1995, with an effective date of June 19, 1995.[9] The 1995 final rule promulgated virtually identical noncitizens'' regulations for the various HUD programs covered by Section 214. On March 27, 1996,[10] HUD published a final rule eliminating the repetitiveness of these duplicative regulations by consolidating the noncitizens requirements in a new subpart E to 24 CFR part 5 (captioned ''Restrictions on Assistance to Noncitizens''), where they continue to be codified at present.

The preamble to the March 20, 1995, final rule stated that, for purposes of eligibility for preservation assistance, HUD considered the effective date of the final rule as the pivotal date rather than the date of enactment of the statute. As noted, the amendments to Section 214 made by the 1987 HCD Act condition a family's eligibility for preservation assistance on the family's receipt of assistance on the date of the statute's enactment. HUD explained in the preamble to the 1995 final rule that it had determined the provisions of Section 214 too ''complex to be determined self-implementing as of the date of enactment of the 1987 HCD Act (February 5, 1988).'' Thus, HUD's regulations use the effective date of the March 20, 1995, final rule (June 19, 1995) as the relevant date for determining eligibility for preservation assistance.

HUD's current regulations require that each family member applying for assistance under a Section 214 covered program either: (1) Submit a declaration declaring that he or she is a U.S. citizen, as defined in 24 CFR 5.504(b), or a noncitizen with eligible immigration status[11]; or (2) elect not to contend eligible immigration status and, therefore, not submit documentation for verification.[12] Family members who declare themselves eligible must provide the original of a document designated by the Department of Homeland Security (DHS) as acceptable evidence of immigration status[13] and consent to transmittal of a copy of the document and the information contained on the document to DHS to verify whether the individual has eligible immigration status.[14] Verification of the immigration status of the individual is provided through Systematic Alien Verification for Entitlements (SAVE), which is administered by DHS.[15] SAVE verifies the immigration status information of noncitizens.

The regulations require that financial assistance made available to a ''mixed family'' be prorated, based on the number of individuals in the family for whom eligibility has been affirmatively established.[16] As noted, Section 214 provides for proration in the context of preservation assistance to mixed families grandfathered by the 1987 HCD Act. However, the amendments made by the 1987 HCD Act limited prorated continued assistance to families with a head of household or spouse in eligible immigration status. In contrast, HUD's current regulations do not require that the head of household or spouse have eligible immigration status in order for a mixed family to qualify for such assistance.

III. This Proposed Rule

This proposed rule would make two changes to the noncitizens regulations in 24 CFR part 5, subpart E. Several factors have prompted HUD to reconsider its noncitizens regulations. On April 10, 2018, President Trump issued Executive Order 13828, titled ''*Reducing Poverty in America by Promoting Opportunity and Economic Mobility.*''[17] Among other provisions, section 2(e) of the Executive order provides that agencies should ''adopt policies to ensure that only eligible persons receive benefits and enforce all relevant laws providing that aliens who are not otherwise qualified and eligible may not receive benefits.'' Further, consistent with the Administration's regulatory reform efforts, HUD has undertaken a comprehensive review of its regulations to reduce unnecessary regulatory burdens, enhance the effectiveness of those regulations that are necessary, and promote principles underlying the rule of law, including ensuring the conformity of regulations with statutory mandates. HUD believes the proposed regulatory amendments are consistent with the principles of Executive Order 13828 and regulatory reform.[18] The policy changes will bring HUD's regulations into greater alignment with the requirements of Section 214 and make the administrative process for verification uniform. The proposed amendments are discussed below:

1. *Verification of eligible immigration status.* The first proposed amendment would require that the eligible immigration status of all recipients of assistance under a Section 214 covered

[3] 42 U.S.C. 1436a(a).

[4] Public Law 100–242, enacted February 5, 1988.

[5] 42 U.S.C. 1436a(d)(2).

[6] 42 U.S.C. 1436a(c)(1)(A).

[7] *Id.*

[8] 42 U.S.C. 1436a(c)(1)(B)(i).

[9] 60 FR 14816.

[10] 61 FR 13614.

[11] § 5.508(c).

[12] § 5.508(e).

[13] § 5.510.

[14] § 5.508(d)(2).

[15] In actuality, the regulations refer to the Immigration and Naturalization Service (INS), a predecessor agency to DHS.

[16] § 5.516(a)(1)(iii).

[17] The Executive order was subsequently published in the **Federal Register** on April 13, 2018 (83 FR 15942), and is available at: *https://www.gpo.gov/fdsys/pkg/FR-2018-04-13/pdf/2018-07874.pdf.*

[18] This proposed rule was also prompted by the March 6, 2017, Presidential Memorandum directing ''[t]he heads of all relevant executive departments and agencies ''[to] issue new rules, regulations, or guidance (collectively, rules), as appropriate, to enforce laws relating to such grounds of inadmissibility and subsequent compliance.'' Although the Presidential Memorandum is focused on the admissibility of aliens into the United States rather than programs of assistance, the proposed regulatory changes are consistent with the directives of the memorandum. *See Implementing Immediate Heightened Screening and Vetting of Applications for Visas and Other Immigration Benefits, Ensuring Enforcement of All Laws for Entry Into the United States, and Increasing Transparency Among Departments and Agencies of the Federal Government and for the American People,* 82 FR 16279 (April. 3, 2017), available at *https://www.gpo.gov/fdsys/pkg/FR-2017-04-03/pdf/2017-06702.pdf.*

program who are under the age of 62 be verified through SAVE.

As noted, the regulations presently excuse individuals from submitting documentation if they do not contend to having eligible immigration status. This results in no actual determination of immigration status being made. The language of Section 214, however, contemplates that HUD assistance under a covered program will generally be contingent on verification of eligible immigration status. While Congress recognized that exceptions to this general verification requirement might be warranted in some cases, this statutory exception is narrowly tailored to individuals 62 years of age or older participating in Section 214 covered programs. In contrast, the ''do not contend'' provision of the regulation is more broadly applicable to all program participants. The proposed change will better conform HUD's regulations to the statutory language of Section 214.

Under the proposed amendment to the rule, a current participant in a Section 214 covered program (with the exception of Section 235 assistance payments) who has not previously submitted evidence of eligible immigration status, will be required to do so at the first regular reexamination after the effective date of HUD's final rule for this rulemaking. This typically occurs on an annual basis. For financial assistance in the form of Section 235 assistance payments, the mortgagor would be required to submit the required evidence in accordance with requirements imposed under the Section 235 Program. The proposed amendment to the rule would not change the timing of verification for new applicants to a Section 214 covered program.

2. *Leaseholder eligibility.* The second proposed regulatory amendment would specify that individuals who are not verified in an eligible immigration status may not serve as the head of household or spouse (*i.e.,* the holder of the lease). As with the prior change, HUD believes this amendment better reflects the statutory requirements of Section 214. In addition, it will better assure that the person who is legally obligated under the lease or other tenancy agreement has been through a uniform identity verification process that would better facilitate locating such person and bringing any necessary administrative or legal actions.

Under the current regulations, the ''do not contend'' provision facilitates the indefinite use by a mixed family of prorated assistance. Further, it is possible under the current regulations for the holder of the lease to be ineligible under the Section 214 covered program for which the mixed family is receiving assistance. Upon reconsideration of its implementing regulations for Section 214, HUD believes that Section 214 requires that no financial assistance be provided to, or on behalf of, an individual if his or her eligible status has not been verified, except for such time that it takes to verify eligible status. In this respect, Section 214 generally provides that ''with respect to a family, the term ''eligibility'' means the eligibility of each family member.'' HUD believes that an individual without verified eligible status living in a mixed household receiving long-term prorated assistance is benefiting from HUD financial assistance in a way that is prohibited by Section 214. At the time of enactment of Section 214, verification was a manual, paper-driven process that could take days or even weeks to complete. Prorated assistance struck a balance with timely permitting assistance but providing an incentive to cooperate in timely completion. Today, verification through SAVE is almost instantaneous in most instances. Thus, prorated assistance should rarely be applicable and then of short duration. The ''do not contend'' provision is inconsistent with the statutory requirements insofar as it permits prorated assistance of unlimited duration.

Further, HUD no longer agrees that a leaseholder, the individual who is contractually bound to the landlord and who holds conditional ownership of the unit for the lease term, can be exempted from having verified eligible immigration status at the outset of the tenancy and assistance. HUD believes that requiring the verified eligible immigration status of the head of household or spouse is more in keeping with the intent of Section 214 to limit eligibility to individuals with eligible immigration status, subject to limited exceptions, and consistent with HUD's existing treatment of leaseholders in its assisted housing programs.

3. *Technical nonsubstantive changes.* In addition to the two substantive amendments discussed above, HUD has taken the opportunity afforded by the proposed rule to make a few technical, nonsubstantive changes to the regulations to further conform to Section 214 statutory requirements. These amendments update terminology and correct formatting. For example, the proposed rule would replace outdated references to the Immigration and Naturalization Service (INS) to refer to DHS.

IV. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.

This rule was determined to be a ''significant regulatory action'' as defined in section 3(f) of the order (although not an economically significant regulatory action under the order). HUD has prepared a cost benefit analysis that addresses the costs and benefits of the proposed rule. The cost analysis is part of the docket file for this rule.

The docket file is available for public inspection in the Regulations Division, Office of the General Counsel, Room 10276, 451 7th Street SW, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the docket file by calling the Regulations Division at (202) 402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay at 1(800) 877–8339 (this is a toll-free number).

Environmental Impact

The proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The proposed regulatory amendments to HUD's noncitizen requirements will have only a minimal impact on small housing project owners, small mortgagees, and small housing agencies. The amendments would not require the creation of new procedures or impose significant additional costs on responsible entities. Rather, the requirements of the proposed rule could be satisfied using existing procedures. For example, the proposed rule would require that the eligible immigration status of all noncitizens be verified through SAVE. This requirement can be fulfilled by utilizing the existing verification procedures. Likewise, although the proposed rule would revise eligibility for prorated assistance, current methods would be used to calculate the prorated assistance provided to an eligible family.

Notwithstanding HUD's determination that this rule will not have a significant effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments nor preempt state law within the meaning of the Executive order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and on the private sector. This proposed rule does not impose a Federal mandate on any State, local, or tribal government, or on the private sector, within the meaning of UMRA.

List of Subjects in 24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Crime, Government contracts, Grant programs-housing and community development, Individuals with disabilities, Intergovernmental relations, Loan programs-housing and community development, Low and moderate income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

Accordingly, for the reasons stated in the preamble, HUD proposes to amend 24 CFR part 5, subpart E as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

■ 1. The authority citation for 24 CFR part 5 continues to read as follows:

Authority: 12 U.S.C. 1701x; 42 U.S.C. 1437a, 1437c, 1437d, 1437f, 1437n, 3535(d); Sec. 327, Pub. L. 109–115, 119 Stat. 2936; Sec. 607, Pub. L. 109–162, 119 Stat. 3051 (42 U.S.C. 14043e *et seq.*); E.O. 13279, 67 FR 77141, 3 CFR, 2002 Comp., p. 258; and E.O. 13559, 75 FR 71319, 3 CFR, 2010 Comp., p. 273.

Subpart E—Restrictions on Assistance to Noncitizens

■ 2. The authority citation for subpart E continues to read as follows:

Authority: 42 U.S.C. 1436a and 3535(d).

■ 3. Amend paragraph (b) of § 5.504 by adding the definition of ''DHS'' in alphabetical order and removing the definitions of ''INS'' and ''Mixed family'' to read as follows:

§ 5.504 Definitions.

* * * * *

(b) * * *

DHS means the Department of Homeland Security.

* * * * *

■ 4. Revise § 5.506(b) to read as follows:

§ 5.506 General provisions.

* * * * *

(b) *Family eligibility for assistance.* (1) A family shall not be eligible for assistance unless every member of the family residing in the unit is determined to have eligible status, as described in paragraph (a) of this section, or unless the family meets the conditions set forth in either paragraph (b)(2) or (3) of this section.

(2) Despite the ineligibility of one or more family members, a family that was receiving assistance under a Section 214 covered program on June 19, 1995, may be eligible for continued assistance, as provided in §§ 5.516 and 5.518. If the family does not qualify for continued assistance, it may nonetheless be eligible for temporary deferral of termination of assistance as provided in §§ 5.516 and 5.518.

(3) A family whose head of household or spouse has eligible immigration status is eligible for prorated assistance under § 5.520, pending final determinations on the eligibility of other family members.

* * * * *

■ 5. Revise § 5.508 to read as follows:

§ 5.508 Submission of evidence of citizenship or eligible immigration status.

(a) *General.* Eligibility for assistance or continued assistance under a Section 214 covered program is contingent upon a family's submission, to the responsible entity, of the documents described in paragraphs (b), (c), and (d) of this section, as applicable, for each family member.

(b) *Evidence of citizenship or eligible immigration status.* Each family member, regardless of age, must submit the following evidence to the responsible entity.

(1) For U.S. citizens as defined in § 5.504(b), the evidence consists of appropriate documentation, such as:

(i) A U.S. birth certificate;

(ii) A naturalization certificate;

(iii) A Consular Report of Birth Abroad (FS–240);

(iv) A valid unexpired U.S. passport;

(v) A certificate of citizenship; or

(vi) Other appropriate documentation, as specified in HUD guidance.

(2) For noncitizens who are 62 years of age or older and were receiving assistance under a Section 214 covered program on September 30, 1996, or who will be 62 years of age or older or applying for assistance on or after that date, the evidence consists of a proof of age document, as may be specified by HUD, and one of the following:

(i) A Form I–551, Permanent Resident Card;

(ii) Form I–94, Arrival/Departure Record;

(iii) A foreign passport with I–551 stamp;

(iv) A notice of approval of status or action from DHS; or

(v) Other appropriate documentation specified by HUD.

(3) For all other noncitizens, the evidence consists of:

(i) A signed declaration of eligible immigration status (see paragraph (c) of this section);

(ii) One of the DHS documents referred to in § 5.510; and

(iii) A signed verification consent form (see paragraph (d) of this section).

(c) *Declaration.* (1) Each family member, regardless of age, must submit to the responsible entity a written declaration, signed under penalty of perjury, by which the family member declares he or she is a U.S. citizen as defined in § 5.504(b) or a noncitizen with eligible immigration status set forth in § 5.506(a)(2).

(i) For each adult, the declaration must be signed by the adult.

(ii) For each child, as defined in § 5.504(b), the declaration must be signed by an adult residing in the assisted dwelling unit who is responsible for the child.

(2) The written declaration may be incorporated as part of the application for housing assistance or may constitute a separate document.

(d) *Verification consent form*—(1) *Who signs.* Each family member, regardless of age, (except certain noncitizens who are 62 years of age or older as described in paragraph (b)(2) of this section) must sign a verification consent form as follows:

(i) For each adult, the form must be signed by the adult.

(ii) For each child, the form must be signed by an adult residing in the assisted dwelling unit who is responsible for the child.

(2) *Notice of release of evidence by responsible entity.* The verification consent form shall provide that evidence of eligible immigration status may be released by the responsible entity, without responsibility for the further use or transmission of the evidence by the entity receiving it, to:

(i) HUD, as required by HUD; and

(ii) DHS to verify the immigration status of the individual.

(3) *Notice of release of evidence by HUD.* The verification consent form shall also notify the individual of the possible release of evidence of eligible immigration status by HUD. Evidence of eligible immigration status shall only be released to DHS for purposes of verifying the individual has eligible immigration status for financial assistance and not for any other purpose. HUD is not responsible for the further use or transmission of the evidence or other information by DHS.

(e) *Notification of requirements of Section 214*—(1) *When notice is to be issued.* Notification of the requirement to submit evidence that the individual is a U.S. citizen, as defined in § 5.504(b), or that individual has eligible immigration status, as required by this section, shall be given by the responsible entity as follows:

(i) *Applicant's notice.* The notification shall be given to each applicant at the time of application for assistance.

(ii) *Notice to tenants.* The notification shall be given to each tenant who has not submitted evidence of eligible status as of [insert effective date of final rule] at the time of, and together with, the responsible entity's notice of regular reexamination of income.

(iii) *Timing of mortgagor's notice.* A mortgagor receiving Section 235 assistance must be provided the notification and any additional requirements imposed under the Section 235 Program.

(2) *Form and content of notice.* The notice shall:

(i) State that financial assistance is contingent upon the submission and verification, as appropriate, of evidence that the individual is a U.S. citizen, as defined in § 5.504(b), or has eligible immigration status;

(ii) Describe the type of evidence that must be submitted, and state the time period in which that evidence must be submitted (see paragraph (f) of this section concerning when evidence must be submitted);

(iii) State that assistance will be denied or terminated, as appropriate, upon a final determination of ineligibility after all appeals, if any, have been exhausted or, if appeals are not pursued, at a time to be specified in accordance with HUD requirements;

(iv) State that assistance may be prorated, pursuant to § 5.520, to a family whose head of household or spouse has eligible immigration status, pending final determinations for other family members; and

(v) Inform tenant's how to obtain assistance under the preservation of families provisions of §§ 5.516 and 5.518.

(f) *When evidence of eligible status is required to be submitted.* The responsible entity shall require evidence of eligible status to be submitted at the times specified in this paragraph (f), subject to any extension granted in accordance with paragraph (g) of this section.

(1) *Applicants.* For applicants, responsible entities must ensure that evidence of eligible status is submitted not later than the date the responsible entity anticipates or has knowledge that verification of other aspects of eligibility for assistance will occur (see § 5.512(a)).

(2) *Tenants.* A tenant who has not submitted evidence of eligible status as of [insert effective date of final rule] is required to submit such evidence as follows:

(i) For financial assistance under a Section 214 covered program, with the exception of Section 235 assistance payments, the required evidence shall be submitted at the first regular reexamination after [insert effective date of final rule], in accordance with program requirements.

(ii) For financial assistance in the form of Section 235 assistance payments, the mortgagor shall submit the required evidence in accordance with requirements imposed under the Section 235 Program.

(3) *New occupants of assisted units.* For any new occupant of an assisted unit (*e.g.,* a new family member comes to reside in the assisted unit), the required evidence shall be submitted at the first interim or regular reexamination following the person's occupancy.

(4) *Changing participation in a HUD program.* Whenever a family applies for admission to a Section 214 covered program, evidence of eligible status is required to be submitted in accordance with the requirements of this subpart unless the family already has submitted the evidence to the responsible entity for a Section 214 covered program.

(5) *One-time evidence requirement for continuous occupancy.* For each family member, the family is required to submit evidence of eligible status only one time during continuously assisted occupancy under any Section 214 covered program.

(g) *Extensions of time to submit evidence of eligible status*—(1) *When extension must be granted.* The responsible entity shall extend the time, provided in paragraph (f) of this section, to submit evidence of eligible immigration status if the family member:

(i) Submits the required declaration described in paragraph (c) of this section certifying that any person for whom required evidence has not been submitted is a noncitizen with eligible immigration status; and

(ii) Certifies that the evidence needed to support a claim of eligible immigration status is temporarily unavailable, additional time is needed to obtain and submit the evidence, and prompt and diligent efforts will be undertaken to obtain the evidence.

(2) *Thirty-day extension period.* Any extension of time, if granted, shall not exceed 30 days. The additional time provided should be sufficient to allow the individual the time to obtain the evidence needed. The responsible entity's determination of the length of the extension needed shall be based on the circumstances of the individual case.

(3) *Grant or denial of extension to be in writing.* The responsible entity's

decision to grant or deny an extension shall be issued to the family by written notice. If the extension is granted, the notice shall specify the extension period granted (which shall not exceed 30 days). If the extension is denied, the notice shall explain the reasons for denial of the extension.

(h) *Failure to submit evidence or to establish eligible status.* If the family fails to submit required evidence of eligible status within the time period specified in the notice, or any extension granted in accordance with paragraph (g) of this section, or if the evidence is timely submitted but fails to establish eligible immigration status, the responsible entity shall proceed to deny, or terminate, assistance or provide continued assistance or temporary deferral of termination of assistance, as appropriate, in accordance with the provisions of §§ 5.514, 5.516, and 5.518.

§ 5.510 [Amended]

■ 6. In § 5.510(b), remove the reference to ''INS'' and add in its place ''DHS''.

■ 7. Revise § 5.512 to read as follows:

§ 5.512 Verification of eligible immigration status.

(a) *General.* Except as described in § 5.514, no individual or family applying for assistance may receive such assistance prior to the verification of the eligibility of at least the head of household or spouse. Verification of eligibility consistent with § 5.514 occurs when the individual or family members have submitted documentation to the responsible entity in accordance with § 5.508.

(b) *Initial verification*—(1) *Verification system.* Verification of the immigration status of the person is conducted by the responsible entity through Systematic Alien Verification for Entitlements (SAVE), a DHS-administered system for the verification of immigration status. Initial verification in SAVE confirms immigration status using biographic information (first name, last name, and date of birth) and immigration numeric identifiers.

(2) *Failure of initial verification to confirm eligible immigration status.* If SAVE is not initially able to confirm immigration status, then additional verification must be performed.

(c) *Additional verification.* If the initial verification does not confirm eligible immigration status, or if initial verification confirms immigration status that is ineligible for assistance under a Section 214 covered program, the responsible entity must request additional verification within 10 days of receiving the results of the initial verification. Additional verification is initiated when the responsible entity submits an s additional request to SAVE with optional additional information and/or a copy of the original document that the noncitizen had presented as acceptable evidence of their immigration status to SAVE.

(d) *Failure to confirm eligible immigration status.* If initial or additional verification does not confirm eligible immigration status, the responsible entity shall issue to the family the notice described in § 5.514(d), which describes the process for seeking record correction with DHS if he or she believes the verification response was due to inaccurate DHS records.

(e) *Exemption from liability for DHS verification.* The responsible entity shall not be liable for any action, delay, or failure of DHS in conducting initial or additional verification.

■ 8. Amend § 5.514 as follows:

■ a. Revise paragraphs (b)(1), (c), and (d); and

■ b. In paragraphs (e), (f), and (h), remove the reference to ''INS'' everywhere it appears and add in its place ''DHS''.

The revisions read as follows:

§ 5.514 Delay, denial, reduction or termination of assistance.

* * * * *

(b) *Restrictions on delay, denial, reduction or termination of assistance*—(1) *Restrictions on reduction, denial or termination of assistance for applicants and tenants.* Assistance to an applicant or tenant shall not be delayed, denied, reduced, or terminated, on the basis of ineligible immigration status of a family member, if:

(i) The SAVE verification of any immigration documents that were timely submitted has not been completed;

(ii) The family member for whom required evidence has not been submitted has moved from the assisted dwelling unit;

(iii) The family member who is determined not to be in an eligible immigration status following the SAVE verification has moved from the assisted dwelling unit;

(iv) Assistance is continued in accordance with §§ 5.516 and 5.518; or

(v) Deferral of termination of assistance is granted in accordance with §§ 5.516 and 5.518.

* * * * *

(c) *Events causing denial or termination of assistance*—(1) *General.* Assistance to an applicant shall be denied, and a tenant's assistance shall be terminated, in accordance with the procedures of this section, upon the occurrence of any of the following events:

(i) Evidence that the individual is a U.S. citizen as defined in § 5.504(b) (*i.e.,* the declaration), or has eligible immigration status, is not submitted by the date specified in § 5.508(f) or by the expiration of any extension granted in accordance with § 5.508(g); or

(ii) Evidence that the individual is a U.S. citizen as defined in § 5.504(b), or has eligible immigration status, is timely submitted, but the SAVE verification does not verify eligible immigration status of a family member.

(2) *Termination of assisted occupancy.* For termination of assisted occupancy, see paragraph (i) of this section.

(d) *Notice of denial or termination of assistance.* The notice of denial or termination of assistance shall advise the family:

(1) That financial assistance will be denied or terminated, and provide a brief explanation of the reasons for the proposed denial or termination of assistance;

(2) In the case of a tenant, the criteria and procedures for obtaining relief under the provisions for preservation of families in §§ 5.516 and 5.518; and

(3) That any family member may seek a record correction with DHS if they believe that SAVE was unable to verify their status due to incorrect immigration records.

* * * * *

■ 9. Revise § 5.516 to read as follows:

§ 5.516 Availability of preservation assistance to tenant families.

(a) *Assistance available for tenant families*—(1) *General.* Preservation assistance may be available to tenant families, in accordance with this section and following the conclusion of a records correction request. There are two types of preservation assistance:

(i) Continued assistance (see § 5.518(a)); and

(ii) Temporary deferral of termination of assistance (see § 5.518(a)).

(2) *Availability of assistance*—(i) *For Housing covered programs.* One of the two types of assistance described in paragraph (a)(1) of this section may be available to tenant families assisted under a National Housing Act or 1965 HUD Act covered program, depending upon the family's eligibility for such assistance. Continued assistance must be provided to a tenant family that meets the conditions for eligibility for continued assistance.

(ii) *For Section 8 or Public Housing covered programs.* One of the two types of assistance described in paragraph (a)(1) of this section may be available to

tenant families assisted under a Section 8 or Public Housing covered program.

(b) *Assistance available to other families in occupancy.* Temporary deferral of termination of assistance may be available to families receiving assistance under a Section 214 covered program on June 19, 1995, and who have no members with eligible immigration status, as set forth in paragraphs (b)(1) and (2) of this section.

(1) *For Housing covered programs.* Temporary deferral of termination of assistance is available to families assisted under a Housing covered program.

(2) *For Section 8 or Public Housing covered programs.* The responsible entity may make temporary deferral of termination of assistance to families assisted under a Section 8 or Public Housing covered program.

(c) *Section 8 covered programs: Discretion afforded to provide certain family preservation assistance*—(1) *Project owners.* With respect to assistance under a Section 8 Act covered program administered by a project owner, HUD has the discretion to determine under what circumstances families are to be provided one of the two statutory forms of assistance for preservation of the family (continued assistance or temporary deferral of assistance). HUD is exercising its discretion by specifying the standards in this section under which a project owner must provide one of these two types of assistance to a family.

(2) *PHAs.* The PHA, rather than HUD, has the discretion to determine the circumstances under which a family will be offered one of the two statutory forms of assistance (continued assistance or temporary deferral of termination of assistance). The PHA must establish its own policy and criteria to follow in making its decision. In establishing the criteria for granting continued assistance or temporary deferral of termination of assistance, the PHA must incorporate the statutory criteria, which are set forth in § 5.518(a) and (b).

■ 10. Amend § 5.518 as follows:

■ a. Revise the section heading and paragraphs (a), (b)(1), (b)(2) introductory text, and (b)(3); and

■ b. Remove paragraph (c) and redesignate paragraph (d) as new paragraph (c).

The revisions read as follows:

§ 5.518 Types of preservation assistance available to tenant families.

(a) *Continued assistance.* A tenant family may receive continued housing assistance if all the following conditions are met (a tenant family assisted under a Housing covered program must be provided continued assistance if the family meets the following conditions):

(1) The family was receiving assistance under a Section 214 covered program on June 19, 1995;

(2) The family's head of household or spouse has eligible immigration status as described in § 5.506; and

(3) The family does not include any person who does not have eligible immigration status other than the head of household, any spouse of the head of household, any parents of the head of household, any parents of the spouse, or any children of the head of household or spouse.

(b) *Temporary deferral of termination of assistance*—(1) *Eligibility for this type of assistance.* If a tenant family does not qualify for continued assistance, the family may be eligible for temporary deferral of termination of assistance, if necessary, to permit the family additional time for the orderly transition of those family members with ineligible status, and any other family members involved, to other affordable housing. Other affordable housing is used in the context of transition of an ineligible family from a rent level that reflects HUD assistance to a rent level that is unassisted; the term refers to housing that is not substandard, that is of appropriate size for the family, and that can be rented for an amount not exceeding the amount that the family pays for rent, including utilities, plus 25 percent.

(2) *Housing covered programs: Conditions for granting temporary deferral of termination of assistance.* The responsible entity shall grant a temporary deferral of termination of assistance to a family if the family is assisted under a Housing covered program and one of the following conditions is met:

* * * * *

(3) *Time limit on deferral period.* If temporary deferral of termination of assistance is granted, the deferral period shall be for an initial period not to exceed six months. The initial period may be renewed for additional periods of six months, but the aggregate deferral period for deferrals shall not exceed a period of eighteen months. These time periods do not apply to a family that includes an individual admitted as a refugee under section 207 of the Immigration and Nationality Act or an individual granted asylum under section 208 of that Act.

* * * * *

■ 11. Revise § 5.520(a) to read as follows:

§ 5.520 Proration of assistance.

(a) *Applicability.* This section applies to a family whose head of household or spouse has eligible immigration status, pending final determinations for other family members.

* * * * *

■ 12. Revise § 5.522 to read as follows:

§ 5.522 Prohibition of assistance to noncitizen students.

The provisions of §§ 5.516 and 5.518 permitting continued assistance or temporary deferral of termination of assistance for certain families do not apply to any person who is determined to be a noncitizen student as in section 214(c)(2)(A) (42 U.S.C. 1436a(c)(2)(A)).

Dated: May 3, 2019.

Benjamin S. Carson, Sr.,

Secretary.

[FR Doc. 2019–09566 Filed 5–9–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–260–FOR; Docket ID: OSM–2018–0008, S1D1S SS08011000 SX064A000 190S180110, S2D2S SS08011000 SX064A000 19XS501520]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Kentucky regulatory program, (herein referred to as 'the Kentucky program'), under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Through this proposed amendment, Kentucky seeks to revise its program to include statutory changes that involve civil penalty escrow accounts, civil penalty fund distributions, self-bonding, and major permit revisions related to underground mining.

This document gives the times and locations that the Kentucky program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the

procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., Eastern Standard Time (e.s.t.), June 10, 2019. If requested, we will hold a public hearing on the amendment on June 4, 2019. We will accept requests to speak at a hearing until 4:00 p.m., e.s.t. on May 28, 2019.

ADDRESSES: You may submit comments, identified by SATS No. KY–260–FOR, Docket ID: OSM–2018–0008, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Michael Castle, Field Office Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503.
- *Fax:* (859) 260–8410.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Kentucky program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Lexington Field Office or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Mr. Michael Castle, Field Office Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503. Telephone: (859) 260–3900, Email: *mcastle@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location: Mr. John D. Small, Acting Commissioner, Kentucky Department for Natural Resources, 300 Sower Boulevard, Frankfort, Kentucky 40601, Telephone: (502) 564–6940, Email: *johnd.small@ky.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Michael Castle, Field Office Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503. Telephone: (859) 260–3900, Email: *mcastle@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Kentucky Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Kentucky program effective May 18, 1982. You can find additional background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and conditions of approval in the May 18, 1982, **Federal Register**, (47 FR 21434). You can also find later actions concerning Kentucky's program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16, and 917.17.

II. Description of the Proposed Amendment

By letter dated September 19, 2018, Kentucky sent OSMRE an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) that includes changes to statutory provisions of the Kentucky Revised Statutes (KRS) (Administrative Record No. KY–2003–01). The General Assembly of the Commonwealth of Kentucky enacted statutory changes through House bill 261 and the changes became effective on July 14, 2018. The statutory changes involve civil penalty escrow accounts, civil penalty fund distributions, self-bonding, and major permit revisions related to underground mining. These changes are codified at KRS Chapter 350, Surface Coal Mining, sections 350.0301, 350.064, 350.070, 350.519, and 350.990. The Kentucky Department for Natural Resources was not required to promulgate administrative regulations as a result of the bill. The revised statutory provisions of 350 KRS are described below.

A. KRS 350.0301, *Petition Challenging the Determination of the Cabinet—Conduct of Hearings—Administrative Regulations—Secretary may Designate Deputy Secretary to Sign Final Orders.* Kentucky seeks to revise KRS 350.0301(5) by removing language requiring civil penalty funds to be placed in escrow prior to a formal hearing on the amount of the assessment of the civil penalties. A provision allowing a waiver of the escrow amount for individuals demonstrating an inability to pay the proposed civil penalty assessment into escrow is also being removed.

B. KRS 350.064, *Reclamation Bond to be filed by Applicant.* Kentucky seeks to revise KRS 350.064(2) by removing language that allows self-bonding in the State. A self-bond is backed only by the company's name and overall financial health, not by sureties or specific pledges of collateral. Currently, in order to qualify and receive state approval for self-bond, the applicant must successfully demonstrate a history of financial solvency and continuous operation and the existence of a suitable agent to receive service of process.

C. KRS 350.070, *Permit Revisions.* Kentucky seeks to revise 350.070(1) by removing language that requires operators to submit a major permit revision application, for an extension of underground mining areas if certain conditions are met (area extension is not considered an incidental boundary revision and does not include planned subsidence or other new proposed surface disturbances). Kentucky also seeks to remove section (6)(b) that defines the maximum acres for a revision to be considered an incidental boundary revision involving underground mining.

D. KRS 350.518, *Permittee to submit permit-specific bond under KRS 350.060(11)—Tonnage Fees—Assignment of Mine Type Classification—Inclusion of Future Permits of Existing Classification—Inclusion of Future Permits of Existing Voluntary Bond Pool Members—Permit-specific Penal Bond—Administrative Regulations—Suspension of Permit for Arrearage in Fees, Rights and Remedies.* Kentucky seeks to delete 350.518(11), which allows penalty funds in excess of $800,000 to be equally divided between the AML supplemental fund and the Kentucky Reclamation Guaranty Fund, herein referred to as ''the Fund.''

E. KRS 350.990, *Penalties.* Kentucky seeks to revise 350.990(1) by removing the requirement to allocate 50% of the civil penalties deposited in excess of $800,000 to the Fund for the purposes set forth in KRS 350.500 to 350.521, and 350.595 (which involve definitions, the Fund Commission, and other matters related to the Fund such as mandatory participation in the Fund, permit-

specific bond requirements, forfeiture of bonds for permits covered by the Fund, and Fund coverage for the AML Enhancement Program) and 50% to the AML supplemental fund established under KRS 350.139(1),

F. *Deposit of Funds to State Treasury—Exceptions—Amount to be Transferred to Fiscal Courts—Remainder for Division of Mine Permits.* Kentucky seeks to add new language that requires civil penalty funds collected over $800,000 to be redistributed to any mining program authorized by KRS Chapters 350, *Surface Mining,* 351, *Department for Natural Resources,* and 352, *Mining Regulations.* Chapters 351 and 352 includes, among other things, mine safety provisions.

In addition to the changes noted above, minor changes such as renumbering and grammatical edits are also included.

The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of Kentucky's State program.

Electronic or Written Comments

If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

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.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., e.s.t. on May 28, 2019. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak, and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

Pursuant to Office of Management and Budget (OMB) Guidance dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We will conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 13, 2018.

Thomas D. Shope,

Regional Director, Appalachian Region.

Editorial note: This document was received for publication by the Office of the Federal Register on May 6, 2019.

[FR Doc. 2019–09560 Filed 5–9–19; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

[SATS No. MO–049–FOR; Docket ID: OSM–2019–0004; S1D1S SS08011000 SX064A000 190S180110; S2D2S SS08011000 SX064A000 19XS501520]

Missouri Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Missouri Abandoned Mine Land Reclamation Fund and Abandoned Mine Reclamation and Restoration regulations (hereinafter, the Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). As a result of Missouri's Red Tape Reduction Initiative (Executive Order 17–03), Missouri proposes amendments to its Plan in order to reduce the volume of these regulations without reducing the Plan's requirements. Missouri also proposes revisions to several sections of its Plan to align with the 2006 amendments to SMCRA and the

subsequent November 14, 2008, changes to the Federal regulations.

This document gives the times and locations where the Missouri Plan and this proposed amendment to that Plan are available for your inspection, establishes the comment period during which you may submit written comments on the amendment, and describes the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., CST, June 10, 2019. If requested, we will hold a public hearing on the amendment on June 4, 2019. We will accept requests to speak at a hearing until 4:00 p.m., CST on May 28, 2019.

ADDRESSES: You may submit comments, identified by SATS No. MO–049–FOR, by any of the following methods:

- *Mail/Hand Delivery:* Joy Schieferstein, Senior Program Specialist, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169.
- *Fax:* (618) 463–6470.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID OSM–2019–0004. If you would like to submit comments go to *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Missouri Plan, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Alton Field Division, or the full text of the Plan amendment is available for you to review at *www.regulations.gov.*

Joy Schieferstein, Senior Program Specialist, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169, Telephone: (618) 463–6460, Email: *jschieferstein@osmre.gov*

In addition, you may review a copy of the amendment during regular business hours at the following location:, Land Reclamation Program, Missouri Department of Natural Resources, 1101 Riverside Drive, Jefferson City, MO 65102–0176, Telephone: (573) 751–4041.

FOR FURTHER INFORMATION CONTACT: Joy Schieferstein, Senior Program Specialist, Alton Field Division. Telephone: (618) 463–6460, Email: *jschieferstein@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Missouri Plan
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Missouri Plan

The Abandoned Mine Land Reclamation Program was established by Title IV of the Act (30 U.S.C. 1201 *et seq.*), in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a Plan) for the reclamation of abandoned coal mines. On the basis of these criteria, the Secretary of the Interior approved the Missouri Plan effective January 29, 1982. You can find background information on the Missouri Plan, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Missouri Plan in the January 29, 1982, **Federal Register** (47 FR 4253). You can also find later actions concerning the Missouri Plan and amendments to the Plan at 30 CFR 925.20 and 925.25.

II. Description of the Proposed Amendment

By letter dated March 6, 2019 (Administrative Record No. MO–685), Missouri sent us an amendment to its Plan under SMCRA (30 U.S.C. 1201 *et seq.*) at its own initiative. Below is a summary of the changes proposed by Missouri. The full text of the Plan amendment is available for you to read at the locations listed above under **ADDRESSES**.

Missouri proposes to amend the following sections of its Abandoned Mine Land Reclamation Fund and Abandoned Mine Reclamation and Restoration regulations to conform to the requirements of Missouri Executive Order 17–03 and to align with the 2006 amendments to SMCRA and the subsequent November 14, 2018, changes to the Federal regulations:

10 CSR 40–9.010—Abandoned Mine Reclamation Fund
10 CSR 40–9.020—General Requirements
10 CSR 40–9.030—Rights of Entry
10 CSR 40–9.040—Acquisition of Land and Water for Reclamation
10 CSR 40–9.050—Management and Disposition of Land and Water
10 CSR 40–9.060—Reclamation on Private Lands

III. Public Comment Procedures

We are seeking your comments on whether the amendment satisfies the applicable plan approval criteria of 30 CFR 884.14 and 884.15. If we approve the amendment, it will become part of the State Plan.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed Plan, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final Plan will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

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.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., CST on May 28, 2019. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under

FOR FURTHER INFORMATION CONTACT. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

Pursuant to Office of Management and Budget (OMB) Guidance dated October 12, 1993, the approval of state program amendments is exempted from OMB review under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a Plan amendment to OSMRE for review, our regulations at 30 CFR 884.14 and 884.15, and agency policy require public notification and an opportunity for public comment. We accomplish this by publishing a notice in the **Federal Register** indicating receipt of the proposed amendment and its text or a summary of its terms. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 925

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 19, 2019.

Alfred L. Clayborne,

Regional Director, Mid-Continent Region.

[FR Doc. 2019–09558 Filed 5–9–19; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[SATS No. OH–259–FOR; Docket ID: OSM–2017–0002; S1D1S SS08011000 SX064A000 190S180110; S2D2S SS08011000 SX064A000 19XS501520]

Ohio Abandoned Mine Land Program and Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Ohio Reclamation Plan (the Ohio Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Through this proposed amendment, Ohio seeks to amend its Abandoned Mine Land (AML) program by revising certain statutory provisions and modifying its AML reclamation plan. The revisions involve incorporating changes to SMCRA requirements (*i.e.,* project eligibility and prioritization), eliminating the 50% match requirement for watershed groups, implementing changes to grant administration requirements, updating organizational changes, and incorporating other program changes. This document gives the times and locations that the Ohio program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., Eastern Standard Time (e.s.t.), June 10, 2019. If requested, we will hold a public hearing on the amendment on June 4, 2019. We will accept requests to speak at a hearing until 4:00 p.m., e.s.t. on May 28, 2019.

ADDRESSES: You may submit comments, identified by SATS No. OH–259–FOR, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220.
- *Fax:* (412) 937–2177.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Ohio program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Pittsburgh Field Division or the full text of the program amendment is available for you to read at *www.regulations.gov.*

Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2827, Email: *bowens@osmre.gov*

In addition, you may review a copy of the amendment during regular business hours at the following location: Mr. Lanny E. Erdos, Chief, Ohio Department of Natural Resources, Division of Mineral Resources Management, 2045 Morse Road, Building H2, Telephone: (614) 265–6893, Email: *lanny.erdos@dnr.state.oh.us.*

FOR FURTHER INFORMATION CONTACT: Mr. Ben Owens, Chief, Pittsburgh Field Division, 3 Parkway Center, Pittsburgh, PA 15220. Telephone: (412) 937–2827, email: *bowens@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Plan
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Ohio Plan

A. Regulatory Program (Title V of SMCRA): Section 503(a) of the Act, *State Programs,* permits a state to assume primacy for the regulation of

surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. *See* 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Ohio program on August 16, 1982. You can find background information on the Ohio program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Ohio program in the August 10, 1982, **Federal Register** (47 FR 34717). You can also find later actions concerning the Ohio program and program amendments at 30 CFR 935.10, *State Regulatory Program Approval;* 935.11, *Conditions of State Regulatory Program Approval;* and 935.15, *Approval of Ohio Regulatory Program Amendments.*

B. AML Program (Title IV of SMCRA): Section 405 of the Act, *State Reclamation Programs,* permits a state to implement an AML reclamation program for the purposes of reclaiming and restoring eligible land and water resources adversely affected by past mining. *See* 30 U.S.C. 1235. This section prescribes the eligibility requirements for approval of State AML programs, minimum content requirements of an AML reclamation plan, submission requirements for the annual AML project listing, and general AML grant requirements. The Federal regulations at 30 CFR part 884 establish the procedures and requirements for the preparation, submission, and approval of state reclamation plans.

On the basis of these criteria, the Secretary of the Interior conditionally approved the Ohio AML program on August 10, 1982. You can find background information on the Ohio AML program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Ohio AML program in the August 10, 1982, **Federal Register** (47 FR 37421). You can also find later actions concerning the Ohio AML program at 30 CFR 935.20, *Approval of Ohio AML Reclamation Plan,* and 935.25, *Approval of Ohio AML Plan Amendments.*

II. Description of the Proposed Amendment

By letter dated March 17, 2017 (Administrative Record No. OH–2195–01), Ohio sent us an amendment that includes statutory changes to its Ohio Revised Code (ORC) as well as changes to its AML reclamation plan under SMCRA (30 U.S.C. 1235) and its implementing regulations at 30 CFR 884.15, *State Reclamation Plan Amendments.* At our request and by letter dated September 15, 2017 (Administrative Record No. OH–2195–04), Ohio resubmitted the amendment to provide additional clarity regarding the changes to the AML plan. On October 1, 2018, Ohio submitted additional changes to the 2016 updated AML plan, which involve public notification of environmental documents related to AML projects (Administrative Record No. OH–2195). The changes to the program as submitted are described below.

A. Statutory Changes—Ohio Revised Code: Ohio submitted Substitute House Bill 471 of the 131st General Assembly (effective December 19, 2016), which affected ORC Section 1513.37, *Abandoned Mine Reclamation Fund.* The statutory revisions of this section reflect revisions to Federal SMCRA provisions, eliminate the 50% match requirement for watershed groups that administer AML reclamation projects, and incorporate changes in AML grants administration and organizational units. The bill also terminated the Council on Unreclaimed Strip Mined Land at 1513.29. The Council was established by law in 2000 and was responsible for reviewing and setting applicable expenditure limits on AML reclamation projects identified by the Ohio Department of Natural Resources. This change was made to implement the recommendations of Ohio's Sunset Review Committee.

B. Ohio AML Plan Changes: Ohio is also seeking to replace its last AML reclamation plan on record with an updated version (2016 Ohio State Reclamation Plan). The last AML reclamation plan amendment was approved on March 26, 1997, and, taken together with the original plan and previously approved amendments, is considered the current approved plan of record. These previously approved amendments, codified at 935.25, *Approval of the Ohio Reclamation Plan Amendments,* involved statutory changes and changes involving the Rural Abandoned Mined Lands Program, staff reorganizations, the AML emergency program, acid mine drainage reclamation, and the project selection process.

The 2016 plan addresses various aspects of the reclamation program, including, but not limited to: Project information (eligibility, ranking and selection); coordination with OSMRE and other agencies; policies regarding reclamation on private land, land acquisition, and rights of entry; public participation; and program management and administration. The plan has been modified to reflect Federal statutory changes, regulatory changes, and changes to Federal grants administration policies and procedures. In addition, changes to Ohio statutory provisions and other program changes, such as organizational changes, are also reflected in the revision. This revised plan replaces the old plan and is revised in parts; redesignated in parts; removed in parts, and added in parts. Minor revisions such as organizational name changes and editorial changes are also included. Federal changes effecting the plan revision are described below.

1. Federal Statutory Changes: There was one major statutory change affecting Title IV of the Act (SMCRA) that occurred since 1997. The change occurred in 2006 through the AML Reauthorization Bill of 2006. This bill extended the AML fee collection authority from 2007 to 2021 and revised the AML program in areas such as the appropriation of funds, allocation formulas, fund objectives and priorities, reclamation lien waivers, AMD set aside accounts, water supply projects, state share payments, remining incentives, and minimum program funding.

2. Federal Regulatory Changes: Changes made to the Federal regulatory provisions, as a result of the aforementioned statutory changes, affecting Ohio's current AML Reclamation Plan of record are as follows: 30 CFR part 872, *Moneys Available to Eligible States and Indian Tribes;* Part 874, *General Reclamation Requirements;* Part 876, *Acid Mine Drainage Treatment and Abatement Program;* Part 879, *Management and Disposition of Lands and Water;* Part 882, *Reclamation on Private Land;* Part 884, *State Reclamation Plans,* and Part 886, *Reclamation Grants for Uncertified States and Indian Tribes.* These regulatory changes involved changes to the definitions of eligible lands and water, interim program eligibility requirements, reclamation objectives and priority designations, reclamation contractor responsibilities, state reclamation grant reporting, grant requirements, water supply projects, AMD set-aside accounts, and government-financed construction projects. *See* 73 FR 67638.

3. Federal Grants Management Changes: The Federal changes affecting Ohio's current AML Reclamation Plan of record involve changes to the President's Office of Management and Budget's (OMB's) Circular A–102, ''Grants and Cooperative Agreements with State and Local Governments.'' The OMB, working cooperatively with

Federal agencies and non-Federal parties, establishes government-wide grants management policies and guidelines through circulars and common rules. Currently, Federal grant funds (including AML grant funds) are governed by the guidelines issued by the OMB. On March 12, 1987, all agencies were directed to issue a common grants management rule to adopt Government-wide terms and conditions for financial assistance to state and local governments (referred to as the Grants Management Common Rule). As a result of the Presidential Order, the grants management guidelines were codified for the Department of the Interior grant programs at 43 CFR part 12 and extensive revisions were made to OSMRE's Federal Assistance Manual (FAM). In addition to the changes to OMB Circular A–102 that resulted from the Common Rule and subsequent revisions that were made to the circular, OSMRE had simplified the AML grant process in 1993, and these changes were also incorporated into the FAM.

C. State/Federal AML Project Coordination: In addition to the statutory changes and plan changes described above, Ohio also submitted changes that involve Federal and State program coordination of AML project responsibilities. Ohio submitted a programmatic agreement between OSMRE, the Ohio History Connection, the State Historic Preservation Office, and the Ohio Department of Natural Resources, Division of Mineral Resources Management. The agreement was signed on January 25, 2017, and formalizes the agreed-upon process for carrying out the responsibilities pursuant to section 106 and section 110(f) of the National Historic Preservation Act and the regulations at 36 CFR part 800.

Ohio asserts that execution and implementation of this agreement is evidence that OSMRE and Ohio have afforded the Advisory Council on Historic Preservation a reasonable opportunity to comment on the AML program, as administered by OSMRE, and that Ohio has taken into account the effects of the program on historic properties under the National Historic Preservation Act (NHPA), associated regulations, and other related statutes. This programmatic agreement describes how AML funds are transferred from OSMRE to the State for the AML program and how coordination regarding NHPA responsibilities will be carried out. This agreement outlines the review and consultation process and includes delegations, personnel, project review procedures, treatment, and resolution of adverse effects. It also addresses post-review discoveries, treatment of human remains, public participation/notification/objections, monitoring and annual reporting/review, dispute resolution, training and technical assistance, and terms of the agreement. It also provides the delegated responsibility to Ohio to make decisions regarding eligibility for properties.

The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov.*

III. Public Comment Procedures

We are seeking your comments on whether the amendment satisfies the applicable plan approval criteria of 30 CFR 884.14 and 884.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

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.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., e.d.t. on May 28, 2019. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT.** We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak, and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

Pursuant to Office of Management and Budget (OMB) Guidance dated October 12, 1993, the approval of State plan amendments are exempted from OMB review under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a state submits a plan amendment to OSMRE for review, our regulations at 30 CFR 884.14 and 884.15, and agency policy require public notification and opportunity for public comment. We accomplish this by publishing a proposed rule notice in the **Federal Register** indicating receipt of the proposed amendment and its text or a summary of its terms. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications

required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 16, 2018.

Thomas D. Shope,

Regional Director, Appalachian Region.

Editorial note: This document was received for publication by the Office of the Federal Register on May 6, 2019.

[FR Doc. 2019–09556 Filed 5–9–19; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2019–0312]

RIN 1625–AA08

Special Local Regulation; Clear Lake, Clear Creek, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a special local regulation for certain waters within Clear Lake, Clear Creek, TX. This action is necessary to provide safety of life on these navigable waters immediately before, during, and after the Texas Outlaw Challenge, a power boat race being held annually on the third Friday of June. This proposed rulemaking would prohibit persons and vessels not participating in the event from being within the specified zone unless authorized by the Captain of the Port Houston/Galveston (COTP) or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 28, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0312 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST3 Sarah Kessler, Waterways Management Division, U.S. Coast Guard; 281–464–4891, *Sarah.A.Kessler@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On April 16, 2019, The Offshore Thunder Productions notified the Coast Guard that they will be hosting a power boat race from 9 to 11:30 a.m. on June 21, 2019. This event will take place in Clear Lake. The COTP has determined that potential hazards associated with the power boat race would be a safety concern for anyone within the Pre-Stage Zone, Approach Zone, Course Run Zone, Shut-Down Zone, and Turn Zone.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the Pre-Stage Zone, Approach Zone, Course Run Zone, and Shut-Down Zone before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

III. Discussion of Proposed Rule

The COTP is proposing to establish a special local regulation from 9 to 11:30 a.m. on the third Friday of June. The special local regulation will encompass 5 different zones to include The Pre-Stage Zone, Approach Zone, Course Run Zone, Shut-Down Zone, and the Spectator Zone as described below:

Pre-Stage Zone: This area is the pre-staging area for participating vessels to line up. It will include all waters within the following areas 29°33.13 N 095°01.84 W, 29°33.12 N 095°01.89 W, 29°33.23 N 095°01.96 W, 29°33.13 N 095°01.84 W.

Approach Zone: ¼ mile distance required for participating vessels to obtain the minimum 40mph requirement for course entry. This will be a straight line to begin at approximately 29°33.256 N, 095°01.89 W and end at approximately 29°33.33 N, 095°02.15 W.

Course Run Zone: ¾ mile distance where participating vessels will conduct their high-speed run. This will be a straight line to begin at approximately 29°33.33 N, 095°02.16 W and end at approximately 29°33.53 N, 095°02.98 W.

Shut-Down Zone: 1 mile distance where participating vessels will be allowed to slow their speeds back to an idle. This will be a straight line to begin at approximately 29°33.53 N, 095°02.98 W and end at approximately 29°33.74 N, 095°04.1 W.

Spectator Zone: All vessels that will be viewing the event will be required to stay within a designated area. The sponsor is responsible for marking the spectator zone with 4 buoys on the outer corners and ensuring that all vessels within the area are anchored and remain in the area during all ongoing high-speed runs.

No vessel or person would be permitted to enter the established zones without obtaining permission from the on-water Safety-Officer or designated representative.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, and duration of the power boat race. The safety zone will impact a small area of Clear Lake for two and one-half hours on June 21, 2019. The Coast Guard will issue a Broadcast notice to Mariners via VHF–FM marine channel 16 regarding the special local regulations, and the zone will allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a special local regulation lasting two and one-half hours that would prohibit entry into the established zones. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *https://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. Amend § 100.801 by adding an entry 7 in Table 3 to read as follows:

§ 100.801 Annual Marine Events in the Eighth Coast Guard District.

* * * * *

TABLE 3 OF § 100.801—SECTOR HOUSTON-GALVESTON ANNUAL AND RECURRING MARINE EVENTS

*	*	*	* * *
7. The 3rd Friday morning in June.	Texas Outlaw Challenge/ Offshore Thunder Productions.	Clear Lake, TX	Clear Lake from the beginning of the Pre Stage Zone to the end of the Shut-Down Zone. *Pre-Stage Zone:* This area is the pre-staging area for participating vessels to line up. It will include all waters within the following areas 29°33.13 N 095°01.84 W, 29°33.12 N 095°01.89 W, 29°33.23 N 095°01.96 W, 29°33.13 N 095°01.84 W. *Approach Zone:* ¼ mile distance required for participating vessels to obtain the minimum 40mph requirement for course entry. This will be a straight line to begin at approximately 29°33.256 N, 095°01.89 W and end at approximately 29°33.33 N, 095°02.15 W. *Course Run Zone:* ¾ mile distance where participating vessels will conduct their high-speed run. This will be a straight line to begin at approximately 29°33.33 N, 095°02.16 W and end at approximately 29°33.53 N, 095°02.98 W. *Shut-Down Zone:* 1 mile distance where participating vessels will be allowed to slow their speeds back to an idle. This will be a straight line to begin at approximately 29°33.53 N, 095°02.98 W and end at approximately 29°33.74 N, 095°04.1 W. *Spectator Zone:* All vessels that will be viewing the event will be required to stay within a designated area. The sponsor is responsible for marking the spectator zone with 4 buoys on the outer corners and ensuring that all vessels within the area are anchored and remain in the area during all ongoing high-speed runs.

* * * * *

Dated: May 3, 2019.

K. D. Oditt,

Captain, United States Coast Guard, Captain of the Port Houston/Galveston.

[FR Doc. 2019–09648 Filed 5–9–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0713: FRL–9993–40-Region 9]

Revisions to California State Implementation Plan; Antelope Valley Air Quality Management District and Ventura County Air Pollution Control District; Nonattainment New Source Review Requirements for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve two state implementation plan (SIP) revisions submitted by the State of California addressing the nonattainment new source review (NNSR) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS) and one SIP revision regarding a permit rule. These SIP revisions address the Antelope Valley Air Quality Management District (AVAQMD or District) and Ventura County Air Pollution Control District (VCAPCD or District) portions of the California SIP. This action is being taken pursuant to the Clean Air Act (CAA or ''Act'') and its implementing regulations.

DATES: Any comments must arrive by June 10, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2018–0713 at *https://www.regulations.gov,* or via email to *R9AirPermits@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Manny Aquitania, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; (415) 972–3977, *aquitania.manny@epa.gov.*

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

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I. Background and Purpose

On March 12, 2008, the EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm).[1] Upon promulgation of a new or revised NAAQS, the CAA requires the EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data. The two California air districts that are subject to this action were designated nonattainment for the 2008 8-hour ozone NAAQS on April 30, 2012, using years 2009–2011 ambient air quality data.[2] At the time of designation, the AVAQMD was classified as a severe ozone nonattainment area as part of the Mojave Desert Air Basin and VCAPCD was classified as a serious ozone nonattainment area as part of the South Central Coast Air Basin.

On March 6, 2015, the EPA issued a final rule entitled, ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements'' (''SIP Requirements Rule''), which establishes the requirements and deadlines that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where ozone concentrations exceed the 2008 8-hour ozone NAAQS.[3] Based on the initial nonattainment designations for the 2008 8-hour ozone standard, each District was required to make a SIP revision addressing nonattainment new source review no later than July 20, 2015.[4] This requirement may be met by submitting a SIP revision consisting of a new or revised NNSR permit program, or an analysis demonstrating that the existing SIP-approved NNSR permit program meets the applicable 2008 ozone requirements and a letter certifying the analysis.

On February 3, 2017, the EPA issued a final rule entitled, ''Findings of Failure to Submit State Implementation Plan Submittals for the 2008 Ozone National Ambient Air Quality Standards'' (''FFS Rule''). The rule found that certain state and local air agencies, including the AVAQMD and VCAPCD, had failed to submit a SIP revision in a timely manner to satisfy specific New Source Review requirements that apply to nonattainment areas. The rule established certain deadlines for the imposition of sanctions, if a state does not submit a timely SIP revision addressing the requirements for which the finding was made, and for the EPA to promulgate a federal implementation plan (FIP) to address any outstanding SIP requirements.

II. The State's Submittal

A. What did the State submit?

Table 1 lists the dates the submitted 2008 Ozone Certification letters and permit rule addressed by this proposal were adopted by each air District and submitted by the California Air Resources Board (CARB), the agency that serves as the governor's designee for California SIP submittals.

TABLE 1—SIP SUBMITTALS

District	Rule No.	Rule title	Adoption/ amend date	Submittal date
AVAQMD	N/A	2008 Ozone Certification	7/17/2018	8/31/2018
VCAPCD	N/A	2008 Ozone Certification	7/31/2018	8/31/2018
VCAPCD	10	Permits Required	4/13/2004	7/19/2004

On August 10, 2004, CARB's July 19, 2004 submittal of VCAPCD's Rule 10 was deemed to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review. On September 6, 2018, CARB's August 31, 2018 submittal of AVAQMD's and VCAPCD's 2008 Certification letters were also deemed to meet the completeness criteria in 40 CFR part 51, appendix V.

B. What is the purpose of the submitted certification letters?

The submittal from each District is intended to satisfy the SIP Requirement Rule that requires states to make a SIP revision addressing nonattainment new source review and the FFS Rule that requires each District to make a SIP submittal by September 6, 2018. The SIP for each District currently contains approved NNSR permit programs based on their nonattainment classification for the 1997 8-hour ozone NAAQS. The submitted certification letters provide a mechanism for each District to satisfy the 40 CFR 51.1114 submittal requirements based on their 2008 8-hr ozone nonattainment designations. EPA's analysis of how these SIP revisions address the NNSR requirements for the 2008 8-hour ozone NAAQS is provided below.

C. What is the purpose of the submitted permit rule?

The submittal of Rule 10 by the VCAPCD is intended to clarify the expiration date of a Part 70 permit. The District revised Section 3, pertaining to the expiration of a ''Permit to Operate'' to clarify that a Part 70 permit does not expire annually, instead it expires only if not renewed in accordance with the requirements of Rule 30, ''Permit Renewal.''

III. Analysis of Nonattainment New Source Review Requirements

The minimum SIP requirements for NNSR permitting programs for the 2008 8-hour ozone NAAQS are contained in 40 CFR 51.165. These NNSR program requirements include those promulgated in the ''Phase 2 Rule'' implementing the 1997 8-hour ozone NAAQS[5] and the SIP Requirements Rule implementing the 2008 8-hour ozone NAAQS. Under the Phase 2 Rule, the SIP for each ozone nonattainment area must contain NNSR provisions that: (1) set major source thresholds for nitrogen oxides (NO_x) and volatile organic compounds (VOC) pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*i*)–(*iv*) and (*2*); (2) classify physical changes at a major source if the change would constitute a major source by itself pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*3*); (3) consider any significant net emissions increase of NO_X as a significant net emissions

[1] 73 FR 16436 (March 27, 2008).

[2] 77 FR 30088 (May 21, 2012).

[3] 80 FR 12263 (March 6, 2015). The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. The rule also revokes the 1997 ozone NAAQS and establishes anti-backsliding requirements.

[4] 40 CFR 51.1114.

[5] 70 FR 71612 (November 29, 2005).

increase for ozone pursuant to 40 CFR 51.165(a)(1)(v)(E); (4) consider any increase of VOC emissions in extreme ozone nonattainment areas as significant net emissions increases and major modifications for ozone pursuant to 40 CFR 51.165(a)(1)(v)(F); (5) set significant emissions rates for VOC and NO_X as ozone precursors pursuant to 40 CFR 51.165(a)(1)(x)(A)–(C) and (E); (6) contain provisions for emissions reductions credits pursuant to 40 CFR 51.165(a)(3)(ii)(C)(*1*)(*2*); (7) provide that the requirements applicable to VOC also apply to NO_X pursuant to 40 CFR 51.165(a)(8); and (8) set offset ratios for VOC and NO_X pursuant to 40 CFR 51.165(a)(9)(ii)–(iv). Under the SIP Requirements Rule, the SIP for each ozone nonattainment area designated nonattainment for the 2008 8-hour ozone NAAQS and designated nonattainment for the 1997 ozone NAAQS as of April 6, 2015, must also contain NNSR provisions that include the anti-backsliding requirements at 40 CFR 51.1105.

A. Antelope Valley Air Quality Management District (AVAQMD)

The AVAQMD's longstanding SIP-approved NNSR program,[6] established in Regulation XIII, ''New Source Review,'' of the AVAQMD's Rules and Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. In addition, the District has submitted revisions to their NSR program that update and clarify certain provisions.[7] The AVAQMD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements and a citation to the specific provision of the SIP-approved or SIP-submitted rule satisfying the requirement. The submittal also includes a certification by the AVAQMD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designation. These documents are available in the docket for this action. EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the AVAQMD's submittal because the current SIP-approved or SIP-submitted NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements for a severe ozone nonattainment area.

B. Ventura County Air Pollution Control District (VCAPCD)

The VCAPCD's longstanding SIP-approved NNSR program,[8] established in Rules 26–26.11, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The VCAPCD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements, and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the VCAPCD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designation. These documents are available in the docket for this action. The EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the VCAPCD's submittal because the current SIP-approved NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements for a serious ozone nonattainment area.

The EPA has determined that the revision to Rule 10 provides clarity pertaining to the expiration of permits issued by the District. Therefore, we find this revision acceptable.

IV. Proposed Action and Public Comment

The EPA is proposing to approve SIP revisions addressing the NNSR requirements for the 2008 8-hour ozone NAAQS for the AVAQMD and VCAPCD, as well as VCAPCD Rule 10. In support of this proposed action, we have concluded that our approval would comply with section 110(l) of the Act because the submittals will not interfere with continued attainment of the NAAQS in each District. The EPA has concluded that the State's submission fulfills the 40 CFR 51.1114 revision requirement and meets the requirements of CAA section 110 and the minimum SIP requirements of 40 CFR 51.165. The intended effect of our proposed action is to approve the submitted certifications as meeting the applicable Phase 2 Rule requirements. If we finalize this action as proposed, our action would incorporate these certifications and Rule 10 into the federally enforceable SIP and be codified through revisions to 40 CFR 52.220 (Identification of plan).

We will accept comments from the public on this proposal until June 10, 2019.

In addition, the FFS Rule issued by the EPA on February 3, 2017 started an 18-month sanctions clock and a 24-month FIP clock.[9] The 18-month sanctions clock was stopped upon receipt of California's SIP revisions and our determination that the submittals were complete. We determined the submittals for AVAQMD and VCAPCD were complete on September 6, 2018. The 24-month FIP clock will stop upon the effective date of our final approval.

V. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the certifications listed in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available electronically through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities

[6] 61 FR 64291 (December 4, 1996).

[7] New Rule 1305—Emission Offsets was submitted to the EPA by CARB on October 30, 2001 and rule revisions were submitted on December 29, 2006.

[8] 65 FR 76567 (December 7, 2000), 68 FR 9561 (February 28, 2003), 75 FR 1284 (January 11, 2010).

[9] 82 FR 9158 (February 3, 2017).

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: April 29, 2019.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2019–09596 Filed 5–9–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 2

[FAR Case 2018–008; Docket No. 2018–0008, Sequence No. 1]

RIN 9000–AN68

Federal Acquisition Regulation: Definition of "Commercial Item"

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a section of the National Defense Authorization Act for Fiscal Year 2018 to revise the definition of a ''commercial item.''

DATES: Interested parties should submit comments to the Regulatory Secretariat Division at one of the addresses shown below on or before July 9, 2019 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments in response to FAR Case 2018–008 by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by entering ''FAR Case 2018–008'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Comment Now'' that corresponds with ''FAR Case 2018–008.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''FAR Case 2018–008'' on your attached document.

• *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Ms. Lois Mandell, 1800 F Street NW, 2nd floor, Washington, DC 20405.

Instructions: Please submit comments only and cite ''FAR case 2018–008'' in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite ''FAR Case 2018–008.''

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to change the definition of ''commercial item'' at FAR 2.101, so that the regulatory definition conforms to statutory changes made to the definition by section 847 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91, enacted December 12, 2017). The rule would broaden the definition to allow certain additional items developed exclusively at private expense to qualify for the benefits associated with being treated as a commercial item. Section 847 amends the definition of ''commercial item'' at 41 U.S.C. 103(8) to expand the universe of nondevelopmental items (NDIs) that qualify as commercial items to include items sold in substantial quantities on a competitive basis to multiple foreign governments.

The statutory and regulatory definition of ''commercial item'' is broad and covers a wide range of products and services. It includes:

• Products, other than real property, that have been offered for sale, lease, or license to the public. Possible indications that an item is commercial are a commercial sales history, listing in catalogs or brochures, an established price, and distributors. Examples of commercial items bought by agencies are transport aircraft, computers, medicine, and fuel. The commercial market is global; commercial items are not limited to the domestic commercial market.

• Products that evolved through advances in technology or performance and will be available in the commercial market in time to meet the delivery requirements of the solicitation. Examples of such items are product updates, model changes, and product improvements such as new versions of software.

• Products that have received minor modifications to meet agency requirements. To be considered minor, a modification may not significantly alter the product's nongovernmental function or essential physical

characteristics. In determining whether a modification is minor, agencies should consider the value and size of the modification and the comparative value and size of the final product.

- Products that were created by integrating commercial subsystems and components into a unique system. For example, a computer system composed of commercial subsystems would be considered a commercial item. Another example is industrial plant equipment that combines commercial components into a unique item based on customer needs.
- Installation services, maintenance services, repair services, training services, and other services procured to support a commercial product. Help desks, call centers, warranty repair services, user training, equipment installation, and other services related to item support are examples.
- Standalone services offered and sold competitively, in substantial quantities, in the commercial marketplace based on established catalog or market prices for specific tasks performed and under standard commercial terms and conditions. Construction, research and development (R&D), warehousing, garbage collection, and transportation of household goods are examples.
- NDIs, if the procuring agency determines the item was developed exclusively at private expense and sold in substantial quantities, on a competitive basis, to multiple State and local governments. NDI is defined separately in FAR 2.101. An NDI includes an item of supply used exclusively for governmental purposes by a Federal agency, a State or local government, or a foreign government with which the United States has a mutual defense cooperation agreement. Examples include—
  - Protective vests used by police departments and rescue equipment used by fire and rescue units;
  - Defense products previously developed by defense agencies of U.S. allies and used exclusively for governmental purposes by Federal agencies, state or local governments, or a foreign government;
  - Items that require only minor modifications to meet the requirements of the procuring agency; and
  - A mechanical dereefer (mechanism for releasing parachute reefing lines) used with the U.S. Army's cargo parachutes that was developed for and first used by the Canadian Army.

II. Discussion and Analysis

This proposed rule will amend the definition of commercial item in FAR part 2 to reflect the statutory change made by section 847. Specifically, the rule would add the phrase ''or to multiple foreign governments'' at the end of paragraph (8).

III. Expected Impact of the Proposed Rule

This rule allows for more transactions to follow requirements for commercial items. This simplifies the transaction in terms of fewer Government reporting requirements and should decrease the cost per transaction for both the Government and the contractor. Under the proposed rule, for the first time, NDIs that are developed exclusively at private expense and sold in substantial quantities to multiple foreign governments may be treated as commercial items.

Because commercial items, which include commercially available off-the-shelf items, are sold to the Government in the same way as NDIs, the Government can take advantage of the previous testing and general acceptance of the product in the commercial marketplace or by a state, local, or foreign government.

To promote the Government's acquisition of commercial items, the law and FAR part 12 create a preference for buying commercial items and provide relief from certain record-keeping, reporting, and compliance requirements. According to an analysis published by the Section 809 Panel in its May 2017 Interim Report, commercial item acquisitions are subject to up to 138 contract clauses, while acquisitions for NDIs that do not meet the commercial item definition as well as acquisitions for non-commercial items could be subject to nearly 500 clauses, depending on the principal type and purpose of the contract. For example, a commercial firm selling an NDI today to multiple foreign governments in substantial quantities could face compliance costs with the Truth In Negotiations Act (TINA), which requires implementation of government-specific business systems for any modifications to competitively awarded items. Policies governing commercial item acquisitions favor reliance on commercial sector business practices and use of standard commercial terms and conditions to the maximum extent practicable. Each of these dimensions of the commercial item framework contributes to more simplified and less costly transactions.

DoD, GSA, and NASA are unable to monetize the cost savings, because procurement data is not captured in a manner that enables a determination to be made regarding how many NDIs developed exclusively at private expense have been sold or are expected to be sold to multiple foreign governments in substantial quantities, that are not also sold in substantial quantities to multiple State and local governments.

Accordingly, DoD, GSA, and NASA welcome feedback, especially from respondents who would expressly benefit from this rulemaking, such as: (i) Identification of any transactional information (*e.g.,* Procurement Instrument Identifiers (PIIDs)) associated with contracts awarded in the past 10 years that would have benefitted from the rule had it been in effect; (ii) any information that might help the regulatory drafters better understand—both qualitatively and quantitatively—the savings and/or cost avoidance that the rule will provide; and (iii) -potential burden reductions associated with future regulatory actions that facilitate broader acquisition of commercial items. In responding to item (ii), respondents are encouraged to discuss, to the extent possible, specific components of savings and cost-avoidance (*e.g.,* identify savings and/or cost-avoidance associated with specific clauses that would no longer be required as a result of this regulatory change).

IV. Applicability To Contract At or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule proposes to amend the FAR to change the definition of ''commercial item''. The revision does not add any new solicitation provisions or clauses, or impact any existing provisions or clauses.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a significant regulatory action and therefore, this rule was not subject to the review of the Office of Information and Regulatory Affairs (OIRA) under section 6(b) of E.O. 12866. This rule is not a major rule under 5 U.S.C. 804.

VI. Executive Order 13771

This proposed rule is expected to be an E.O. 13771 deregulatory action. Details are provided in section III of this preamble.

VII. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601 *et seq.* However, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to change the definition of ''commercial item'' so that NDIs that are developed exclusively at private expense and sold in substantial quantities to multiple foreign governments may be treated as commercial items.

The objective is to implement section 847 of the NDAA for FY18. The legal basis for this rule is 41 U.S.C. 103(8).

The proposed rule impacts all entities who do business with the Federal Government, including the over 327,458 small business registrants in the System for Award Management database. This proposed rule expands the definition of ''commercial item'' for nondevelopmental items (NDIs) to include those sold to multiple foreign governments. This change will allow more acquisitions to fall under the definition of commercial item procurements and use standard commercial terms and conditions to the maximum extent practicable. This will result in a reduction of statutory and regulatory requirements as FAR part 12 contract actions are exempt at the prime or subcontract level from various statutes, policies, and contracting requirements unique to the federal procurement process. Therefore, small businesses would benefit from the streamlined processes.

The proposed rule does not include additional reporting or record keeping requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no available alternatives to the proposed rule to accomplish the desired objective of the statute. Small businesses will benefit from the streamlined commercial acquisition procedures.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule consistent with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2018–008) in correspondence.

VIII. Paperwork Reduction Act

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

List of Subjects in 48 CFR Part 2

Government procurement.

Dated: April 22, 2019.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA are proposing to amend 48 CFR part 2 as set forth below:

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 1. The authority citation for 48 CFR part 2 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

2.101 [Amended]

■ 2. In paragraph (b)(2), amend paragraph (8) in the definition of ''Commercial item'' by removing ''local governments'' and adding in its place ''local governments or to multiple foreign governments''.

[FR Doc. 2019–09703 Filed 5–9–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 190214116–9116–01]

RIN 0648–BI69

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Fishing Year 2019 Recreational Management Measures

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes fishing year 2019 recreational management measures for Gulf of Maine cod and haddock and Georges Bank cod. This action is necessary to respond to updated catch and other scientific information. The proposed measures are intended to ensure the recreational fishery achieves, but does not exceed, its fishing year 2019 catch limits.

DATES: Comments must be received by May 28, 2019.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2018–0140, by either of the following methods:

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

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018–0140.*

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

3. Enter or attach your comments.

• *Mail:* Submit written comments to: Michael Pentony, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on the Fishing Year 2019 Groundfish Recreational Measures.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the analyses supporting this rulemaking, including the Framework Adjustment 57 environmental assessment (EA) prepared by the New England Fishery Management Council are available from: Michael Pentony, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. The supporting documents are also accessible via the internet at: *http://www.nefmc.org/management-plans/northeast-multispecies* or *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Management Specialist, phone: 978–281–9116; email: *Emily.Keiley@noaa.gov.*

SUPPLEMENTARY INFORMATION:

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1. Proposed Gulf of Maine Recreational Management Measures for Fishing Year 2019
2. Proposed Georges Bank Cod Recreational Management Measures for Fishing Year 2019

1. Proposed Gulf of Maine Recreational Management Measures for Fishing Year 2019

Background

The recreational fishery for Gulf of Maine (GOM) cod and haddock is managed under the Northeast Multispecies Fishery Management Plan (FMP). The multispecies groundfish fishery opens on May 1 each year and runs through April 30 of the following calendar year. The FMP sets sub-annual catch limits (sub-ACL) for the recreational fishery each fishing year for both species. These sub-ACLs are a fixed proportion of the overall catch limit for each stock. The FMP also includes proactive recreational accountability measures (AM) to prevent the recreational sub-ACLs from being exceeded and reactive AMs to correct the cause or mitigate the effects of an overage if one occurs.

The proactive AM provision in the FMP requires the Regional Administrator, in consultation with the New England Fishery Management Council, to develop recreational management measures for the upcoming fishing year to ensure that the recreational sub-ACL is achieved, but not exceeded. The provisions authorizing this action can be found in the FMP's implementing regulations at 50 CFR 648.89(f)(3).

According to the 2017 stock assessments, the GOM cod and haddock stocks are increasing, although cod remains overfished and subject to a rebuilding plan. Framework Adjustment 57 to the FMP set 2018 and 2019 ACLs and sub-ACLs based on the updated assessments. Framework 58, as approved by the Council, does not adjust the fishing year 2019 recreational sub-ACLs for GOM cod or haddock, and the 2019 sub-ACLs remain at the same level as in 2018. The 2019 recreational sub-ACL for GOM cod is 220 mt, the 2019 recreational sub-ACL for GOM haddock is 3,358 mt.

Compared to preliminary estimates of 2018 catch, the fishing year 2019 sub-ACLs would allow for a 379-percent increase in haddock catch, and a 57-percent increase in cod catch (Table 1). Status quo measures are projected to result in cod and haddock catch below the 2019 sub-ACLs.

TABLE 1—PRELIMINARY FISHING YEAR 2018 CATCH COMPARED TO FISHING YEAR 2018 AND 2019 SUB-ACLS

GOM Stock	2018 and 2019 sub-ACLs (mt)	Estimated 2018 catch (mt)	Percent of FY 2018 sub-ACL caught	Change in 2018 catch to reach 2019 sub-ACL (percent)
Cod	220	140	64	57
Haddock	3,358	700	21	379

2019 Council Consultation Process and Timing

The analysis of potential recreational measures was delayed by the partial Federal government shutdown, and, as a result, the Council's Recreational Advisory Panel (RAP) was unable to meet prior to the January Council meeting. At the January 2019 meeting, the Council passed a motion to modify the consultation process this year, authorizing the Executive Committee to make final Council recommendations to the agency. The RAP met and developed recommendations on February 22, 2019. The Groundfish Committee reviewed the RAP's recommendations at its February 26 meeting. The Executive Committee reviewed both sets of recommendations by correspondence. Table 2 summarizes the recommendations made by the RAP and Groundfish Committee. As authorized by and on behalf of the Council, the Council's Executive Committee recommended that we adopt measures as proposed by the Groundfish Committee.

TABLE 2—SUMMARY OF THE STATUS QUO MEASURES AND THE MEASURES RECOMMENDED BY THE RAP, GROUNDFISH COMMITTEE, AND EXECUTIVE COMMITTEE

Option	GOM haddock			GOM cod		
	Daily possession limit	Minimum size	Open season	Daily possession limit	Minimum size	Open season
Status Quo	12	17″ (43.2 cm)	May 1–Sept 16; Nov 1–Feb 28; Apr 15–Apr 30.	Closed.		
RAP Preferred	15	15″ (31.1 cm)	All Year	1	19″ (2.9 cm)	Aug and Apr.
RAP Backup	15	15″ (31.1 cm)	All Year	1	21″ (51.3 cm)	Aug and Apr.
Groundfish Committee.	15	15″ (31.1 cm)	May 1–Feb 28; Apr 15–Apr 30.	1	21″ (51.3 cm)	Sept 15–30; Apr 15–Apr 30.

Analysis and Uncertainty

Preliminary estimates of GOM cod and haddock catch for fishing year 2018 indicate that the recreational fishery will not achieve the 2018 sub-ACL of either stock. The bioeconomic model projects that measures for both stocks can be liberalized without the 2019 recreational fishery's sub-ACLs being exceeded. The bioeconomic model's predicted probabilities that catch will remain at or below the sub-ACLs are informative. However, the model frequently underestimates effort and catch, resulting in the selection of

management measures that do not successfully constrain catch to the sub-ACL. In recent years, despite utilization of the bioeconomic model to inform management measures, the recreational fishery exceeded their sub-ACL for GOM cod four out of five years and, in two of those years, this contributed to overages of the acceptable biological catch (ABC).

The Marine Recreational Information Program (MRIP) data used in the bioeconomic model are also highly variable from year to year. Data from the MRIP are processed throughout the fishing year as new data arrive for each wave (2-month periods), and older data are updated as needed. Incorporation of new waves, or updates, may result in changes to the model output. This combination of factors makes it difficult to produce consistent predictions and to assess the underlying reasons for the discrepancies between the model's predicted catch and estimates of actual catch.

This year, in addition to the uncertainty described above, there are several factors that, when combined, make this particular year's model estimates more uncertain than in any other year we have used the model:

(1) The bioeconomic model is relying on projections from stock assessments that are 3 years beyond the assessments' terminal year. Projections from stock assessments become inherently more uncertain as time progresses. The last assessment for GOM cod and haddock occurred in 2017, and the last year of data used in those assessments was from 2016. The bioeconomic model uses these projections to inform assumptions about the population structure. Utilization of projections from that model to inform what is happening to the stocks in fishing year 2019 and 2020 is highly uncertain.

(2) MRIP catch and effort estimates (1981–2017) based on the Coastal Household Telephone Survey (CHTS) were transitioned to the new, mail-based Fishing Effort Survey (FES). However, the most recently available stock assessments and sub-ACLs were based on the CHTS estimates. Evaluation of catch and development of management measures will continue to use data in the CHTS-equivalent until new assessments are conducted for these two stocks using FES information. That means, for fishing year 2018, FES data had to be converted back into CHTS values. The introduction of another model (back-calibration from CHTS to FES) and the associated assumptions adds a new layer of uncertainty.

(3) The bioeconomic model is predicting effort and behavior in months that have been closed in recent years. The bioeconomic model uses behavior (effort and catch) in the previous year, in this case fishing year 2018, to tune the model to predict what is likely to occur in the next fishing year. This creates a challenge when the model needs to predict behavior during time periods that have been closed in the prior year. It is more difficult, and there is additional uncertainty when trying to model less restrictive management measures.

Given the potentially significant uncertainty in the model estimates from this combination of factors, the Groundfish Plan Development Team and members of the RAP suggested re-running the model using averaged MRIP data and different assumptions about recruitment. Due to time constraints, these analyses could not be produced in time for consideration by the RAP, Groundfish Committee, or the Executive Committee. We are including the results in this proposed rule.

We conducted sensitivity runs to evaluate alternatives using different assumptions within the bioeconomic model to capture some of the uncertainty described above. To reduce the uncertainty associated with using back-calibrated MRIP data for fishing year 2018, the bioeconomic model was re-calibrated to use the average MRIP effort estimate from fishing years 2016–2018 (152,340 angler trips) instead of the fishing year 2018 value (124,994 angler trips). Using an average that includes 2 years of data that was not back calibrated may address some of the uncertainty associated with the back calibration of 2018 data. Using the average effort results in higher estimated cod and haddock mortality in fishing year 2019 under all of the options. To address some of the biological projection uncertainty since the terminal year of the current assessment is from 2016, we replaced the 2019 projections with the 2017 projected stock structure. This provides a far less optimistic view of recruitment, which based on recent surveys is likely more realistic. This assumption results in slightly higher average cod catch-per-trip (by weight) in the model's projections and increases cod mortality across all of the options.

TABLE 3—FISHING YEAR 2019 GOM COD AND HADDOCK PROJECTIONS FROM THE BIOECONOMIC MODEL

[Sensitivity model run results in italics]

Option	GOM haddock			GOM cod			Predicted haddock catch (mt	Predicted cod catch (mt)
	Daily possession limit	minimum size	Open season	Daily possession limit	minimum size	Open season		
Status Quo	12	17″ (43.2 cm)	May 1–Sept 16; Nov 1–Feb 28; Apr 15–Apr 30.	Closed.			791 (*839*)	114 (*154*)
RAP Preferred	15	15″ (31.1 cm)	All Year	1	19″ (22.9 cm)	Aug and Apr	1,024 (*1,061*)	138 (*201*)
RAP Backup	15	15″ (31.1 cm)	All Year	1	21″ (51.3 cm)	Aug and Apr	1,022 (*1,060*)	134 (*196*)
Council Recommended NMFS Proposed.	15	17″ (43.2 cm)	May 1–Feb 28; Apr 15–Apr 30.	1	21″ (51.3 cm)	Sept 15–30; Apr 15–Apr 30.	992 (*1,047*)	125 (*179*)

Proposed Measures

Given the previously described uncertainty in the model estimates, the Groundfish Committee and Executive Committee recommended more conservative measures than the RAP, while still allowing a limited directed cod fishery. The Committees' preferred option also increases access to the healthy haddock stock. We are proposing the Council's recommended measures (see Table 4). While the bioeconomic model suggests that the RAP preferred and backup options would result in cod catch less than the 220 mt sub-ACL, the uncertainty associated with those projections is high. The bioeconomic model attempts to describe the impact directed haddock fishing has on cod mortality in the Gulf

of Maine, as the two stocks are often found together. The model shows that proposed measures for haddock are likely to increase cod interactions, and therefore mortality. The degree to which the new haddock measures will affect cod mortality is highly uncertain because the model is predicting behavior in months that were previously closed (see #3 above).

GOM cod is overfished and subject to overfishing. The recreational fishery has exceeded its GOM cod sub-ACL in four of the last five years. These overages have contributed to two overages of the total ACL and ABC. The more precautionary proposed measures take into account some of the uncertainty described above to reduce the chance of exceeding the GOM cod recreational sub-ACL while increasing the opportunity for the recreational fishery to achieve the recreational sub-ACLs. Given the uncertainty, condition of the GOM cod stock, and recent history of recreational management performance, we agree with the Council and Groundfish Committee that a more precautionary approach is needed this year, and we are therefore, proposing their recommended measures.

TABLE 4—STATUS QUO AND PROPOSED 2019 RECREATIONAL MANAGEMENT MEASURES FOR GOM COD AND HADDOCK

	GOM haddock			GOM cod		
	Daily possession limit	Minimum size	Open season	Daily possession limit	Minimum size	Open season
2018 Measures	12	17″ (43.2 cm)	May 1–Sep 16; Nov 1–Feb 28/29; April 15–Apr 30.	Closed.		
2019 Proposed	15	17″ (43.2 cm)	May 1–Feb 28/29; Apr 15–Apr 30.	1	21″ (51.3 cm)	Sept 15–30; Apr 15–Apr 30.

2. Fishing Year 2019 Georges Bank Cod Recreational Management Measures

Background

As part of Framework 57 to the FMP, the Council provided the Regional Administrator authority to adjust the GB cod recreational management measures for fishing years 2018 and 2019. Unlike GOM cod and haddock, there is no recreational sub-ACL for GB cod and no accountability measures for the recreational fishery when an overage occurs. The Council did not consider a recreational sub-ACL in Framework 57, but the Council recommended a catch target of 138 mt for us to use when considering adjustments to GB cod measures. The catch target was based on the most recent 5-year (calendar years 2012–2016) average recreational catch. The Council expects that measures designed to achieve this target amount for the recreational fishery will help the overall fishery attain, but not exceed, its overall ACL. We adjusted recreational GB cod measures for fishing year 2018. This was the first time GB cod recreational measures had been changed since 2010. We increased the minimum size by 1 inch (2.54 cm) (from 22 to 23 in, 55.9 to 58.4 cm) and reduced the unlimited for-hire (party/charter) bag limit to 10 fish per person, consistent with private vessel's bag limit. To avoid using potentially anomalous results from the highly variable MRIP catch estimates for GB cod, we used a 3-year average catch estimate to better represent long-term trends. We then compared that catch estimate with the catch target to determine if adjustments to the management measures were needed. Because the 3-year average was higher than the catch target, we adjusted fishing year 2018 measures as described above.

This year, the Council asked that we consider alternative methods to evaluate GB cod catch and examine management needs. Even if the preliminary catch estimate for 2018 was zero, the 3-year average would still be greater than the catch target of 138 mt due to an extremely high 2016 catch estimate.

Proposed Measures

Catch of GB cod was substantially less in 2017 (53 mt) compared to 2016 (477 mt). Preliminary estimates of 2018 catch (57 mt) are similar to 2017, indicating that estimated 2016 catch may have been an anomaly (Table 5).

TABLE 5—RECREATIONAL CATCH OF GB COD FROM FISHING YEAR 2013–2018 AND THE 3-YEAR MOVING AVERAGE CATCH

Fishing year	Catch (mt)	3-Year average catch (mt)
2013	8.0	.....
2014	91.4	.....
2015	165.0	88.1
2016	477.5	244.6
2017	53.0	231.8
2018*	57.0	195.8

*Catch in 2018 is an estimate.

Given that 2017 and 2018 catch levels are low compared to the catch target, the Executive Committee recommended liberalizing management measures for GB cod, reducing the minimum size from 23 inches to 21 inches (58.4 to 53.3 cm). The Executive Committee's recommendation is consistent with the Groundfish Committee's recommendation. The RAP proposed a lower minimum size of 19 inches (48.3 cm). We propose the Council's recommendations for GB cod (see Table 6). A 21-inch (53.3-cm) minimum fish size is consistent with the minimum

size proposed for GOM cod and is expected to increase catch by approximately 20 percent (based on size frequencies of 2018 catch). Decreasing the minimum size will allow anglers to retain fish they would have caught and then discarded. The estimated increase in catch would still result in catch lower than the catch target, if effort in 2019 is similar to 2017 and 2018. Given the variability and uncertainty in the GB cod MRIP estimates, a precautionary approach to revising measures is warranted to ensure that the catch target and ACL are not exceeded. In addition, having consistent minimum sizes in GOM and GB is likely to increase compliance.

TABLE 6—GB COD STATUS QUO AND PROPOSED 2019 MEASURES

	Georges Bank cod		
	Daily possion limit	Minimum size	Open season
2018 Measures	10	23″ (58.4 cm)	All Year.
2019 Proposed	10	21″ (53.3 cm)	All Year.

Classification

The NMFS Assistant Administrator has made a preliminary determination that this proposed rule is consistent with the Northeast Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866.

The Assistant Administrator for Fisheries finds good cause to have a 15-day comment period in accord with the Administrative Procedures Act and as provided for in the Magnuson-Stevens Act. This rule proposes more liberal management measures for GOM cod, haddock, and GB cod compared to current recreational management measures. The Northeast multispecies fishing year begins on May 1 of each year and continues through April 30 of the following calendar year. Further delaying final action on these proposed measures to allow for a longer comment period than the minimum 15-day amount allowed for by the Magnuson-Stevens Act negatively impacts business planning for the for-hire segment of the fishery, causes confusion in the fishery, and may result in less compliance with the regulations. Additionally, further delay would diminish the value to the public of increasing the haddock possession limit because haddock are abundant near shore during April–June, making this an important season for the recreational haddock fishery. We could not have completed the proposed rule earlier because of the availability of recreational data from MRIP and the required consultation process with the New England Fishery Management Council. This rule is straightforward, and proposes changes that were discussed during a series of public meetings. These are yearly measures that are familiar to and anticipated by fishery participants. Affected and other interested parties participated in the Council's process to develop this action. Use of a longer comment period would further delay the implementation of new recreational management measures which would increase negative economic impacts on affected parties.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows.

The SBA defines a small commercial finfishing or shellfishing business as a firm with annual receipts (gross revenue) of up to $11.0 million. A small for-hire recreational fishing business is defined as a firm with receipts of up to $7.5 million. Having different size standards for different types of fishing activities creates difficulties in categorizing businesses that participate in multiple fishing related activities. For purposes of this assessment business entities have been classified into the SBA-defined categories based on which activity produced the highest percentage of average annual gross revenues from 2015–2017, the most recent 3-year period for which data are available. This classification is now possible because vessel ownership data have been added to Northeast permit database. The ownership data identify all individuals who own fishing vessels. Using this information, vessels can be grouped together according to common owners. The resulting groupings were treated as a fishing business for purposes of this analysis. Revenues summed across all vessels in a group and the activities that generate those revenues form the basis for determining whether the entity is a large or small business.

A for-hire owner and operator can be held liable for violations of the proposed regulations; thus, for-hire business entities are considered directly affected in this analysis. Private anglers are not considered ''entities'' under the Regulatory Flexibility Act (RFA).

The Northeast Federal landings database (*i.e.,* vessel trip report data) indicates that a total of 614 vessels held a multispecies for-hire fishing permit in 2017 (the most recent full year of available data). Of the 614 for-hire permitted vessels only 163 actively participated in the for-hire Atlantic cod and haddock fishery in fishing year 2017 (*i.e.,* reported catch of cod or haddock).

Using vessel ownership information and vessel trip report data it was determined that the 163 actively participating for-hire vessels are owned by 153 unique fishing business entities. The vast majority of the 153 fishing businesses were solely engaged in for-hire fishing, but some also earned revenue from shellfish and/or finfish fishing. The highest percentage of annual gross revenues for all but 20 of the fishing businesses was from for-hire fishing.

Average annual gross revenue estimates calculated from the most recent three years (2015–2017) indicate that none of the 153 fishing business entities had annual receipts of more than $2.8 million from all of their fishing activities (for-hire, shellfish, and finfish). Therefore, all of the affected fishing business entities are considered ''small'' by the SBA size standards and thus this action will not disproportionately affect small versus large for-hire business entities.

The measures proposed are expected to have a positive economic effect on small entities. The proposed measures could increase catch and effort, in a scenario when fishing would otherwise be prohibited. Providing increased

fishing opportunities should increase profits.

This action is not expected to have a significant or substantial effect on small entities. The effects on the regulated small entities identified in this analysis are expected to be positive relative to maintaining the measures in place from 2018. The proposed action liberalizes recreational management measures for GOM cod and haddock and Georges Bank cod. Under the proposed action, small entities would not be placed at a competitive disadvantage relative to large entities, and the regulations would not reduce the profit for any small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: May 7, 2019.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.89, revise paragraphs (b)(1), (c)(1) and (2) as follows:

§ 648.89 Recreational and charter/party vessel restrictions.

* * * * *

(b) * * *

(1) *Minimum fish sizes.* Unless further restricted under this section, persons aboard charter or party boats permitted under this part and not fishing under the NE multispecies DAS program or under the restrictions and conditions of an approved sector operations plan, and private recreational fishing vessels may not possess fish in or from the EEZ that are smaller than the minimum fish sizes, measured in total length, as follows:

Species	Minimum size	
	Inches	cm
Cod:		
Inside GOM Regulated Mesh Area [1]	21	53.3
Outside GOM Regulated Mesh Area [1]	21	53.3
Haddock:		
Inside GOM Regulated Mesh Area [1]	17	43.2
Outside GOM Regulated Mesh Area [1]	18	45.7
Pollock	19	48.3
Witch Flounder (gray sole)	14	35.6
Yellowtail Flounder	13	33.0
American Plaice (dab)	14	35.6
Atlantic Halibut	41	104.1
Winter Flounder (black back)	12	30.5
Redfish	9	22.9

[1] GOM Regulated Mesh Area specified in § 648.80(a).

* * * * *

(c) * * *

(1) *Private recreational vessels.* Persons aboard private recreational fishing vessels during the open season listed in the column titled ''Open Season'' in Table 1 to paragraph (c) of this section, may not possess more fish in or from the EEZ than the amount listed in the column titled ''Possession Limit'' in Table 1 to paragraph (c) of this section.

(i) *Closed season.* Persons aboard private recreational fishing vessels may not possess species, as specified in the column titled ''Species'' in Table 1 to paragraph (c) of this section, in or from the EEZ during that species closed season as specified in the column titled ''Closed Season'' in Table 1 to paragraph (c) of this section.

TABLE 1 TO PARAGRAPH (c)

Species	Open season	Possession limit	Closed season
GB Cod	All Year	10	N/A.
GOM Cod	September 15–30; April 15–30	1	May 1–September 14; October 1–April 14.
GB Haddock	All Year	Unlimited	N/A.
GOM Haddock	May 1–February 28 (or 29); April 15–30.	12	March 1–April 14.
GB Yellowtail Flounder	All Year	Unlimited	N/A.
SNE/MA Yellowtail Flounder	All Year	Unlimited	N/A.
CC/GOM Yellowtail Flounder	All Year	Unlimited	N/A.
American Plaice	All Year	Unlimited	N/A.
Witch Flounder	All Year	Unlimited	N/A.
GB Winter Flounder	All Year	Unlimited	N/A.
GOM Winter Flounder	All Year	Unlimited	N/A.
SNE/MA Winter Flounder	All Year	Unlimited	N/A.
Redfish	All Year	Unlimited	N/A.
White Hake	All Year	Unlimited	N/A.
Pollock	All Year	Unlimited	N/A.
N. Windowpane Flounder	CLOSED	No retention	All Year.
S. Windowpane Flounder	CLOSED	No retention	All Year.

TABLE 1 TO PARAGRAPH (c)—Continued

Species	Open season	Possession limit	Closed season
Ocean Pout	CLOSED	No retention	All Year.
Atlantic Halibut	See paragraph (c)(3).		
Atlantic Wolffish	CLOSED	No retention	All Year.

(2) *Charter or Party Boats.* Persons aboard party or charter boats during the open season listed in the column titled ''Open Season'' in Table 2 to paragraph (c) of this section, may not possess more fish in or from the EEZ than the amount listed in the column titled ''Possession Limit'' in Table 2 to paragraph (c) of this section.

TABLE 2 TO PARAGRAPH (c)

Species	Open season	Possession limit	Closed season
GB Cod	All Year	10	N/A.
GOM Cod	September 15–30; April 15–30	1	May 1–September 14; October 1–April 14.
GB Haddock	All Year	Unlimited	N/A.
GOM Haddock	May 1–February 28 (or 29); April 15–30.	12	March 1–April 14.
GB Yellowtail Flounder	All Year	Unlimited	N/A.
SNE/MA Yellowtail Flounder	All Year	Unlimited	N/A.
CC/GOM Yellowtail Flounder	All Year	Unlimited	N/A.
American Plaice	All Year	Unlimited	N/A.
Witch Flounder	All Year	Unlimited	N/A.
GB Winter Flounder	All Year	Unlimited	N/A.
GOM Winter Flounder	All Year	Unlimited	N/A.
SNE/MA Winter Flounder	All Year	Unlimited	N/A.
Redfish	All Year	Unlimited	N/A.
White Hake	All Year	Unlimited	N/A.
Pollock	All Year	Unlimited	N/A.
N Windowpane Flounder	CLOSED	No retention	All Year.
S Windowpane Flounder	CLOSED	No retention	All Year.
Ocean Pout	CLOSED	No retention	All Year.
Atlantic Halibut	See Paragraph (c)(3)		
Atlantic Wolffish	CLOSED	No retention	All Year.

* * * * *

[FR Doc. 2019–09685 Filed 5–9–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 84, No. 91
Friday, May 10, 2019

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 Meeting of the Hawaii 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 Hawaii Advisory Committee (Committee) will hold a meeting via teleconference on Friday, May 24, 2019, from 12:00 p.m.–1:00 p.m. (Hawaii Time) for the purpose of reviewing the Micronesian Barrier to Equal Opportunity report.

DATES: The meeting will be held on Friday, May 24, 2019, from 12:00 p.m.–1:00 p.m. (HDT)

Teleconference: The public may participate via conference call by calling (877) 260–1479 and use Conference ID #6880139.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or 312–353–8311.

SUPPLEMENTARY INFORMATION: This meeting is open to the public. The public can access this meeting by calling 877–260–1479 and using access code 6880139. To request individual accommodations for persons with disabilities planning to attend, please contact the Regional Programs Unit at 312–353–8311. Members of the public are also 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 David Barreras at *dbarreras@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, Hawaii Advisory Committee link (*https://gsageo.force.com/FACA/apex/FACAPublicCommittee?id=a10t0000001gzl0AAA*). 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 Office at the above email or street address.

Agenda

Opening Remarks and Introductions (12:00 p.m.)
Roll Call
Discussion of Micronesian Barriers to Equal Opportunity Report
Public Comment
Adjournment

Dated: May 6, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–09642 Filed 5–9–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–912 and C–570–913]

Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Final Results of Sunset Reviews and Revocation of Antidumping Duty and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is revoking the antidumping duty and countervailing duty orders on certain new pneumatic off-the-road tires (OTR Tires) from the People's Republic of China (China).

DATES: Applicable February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Thomas Dunne or Jacqueline Arrowsmith AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2328 or (202) 482–5255, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 4, 2008, Commerce issued antidumping duty and countervailing duty orders on OTR Tires from China.[1] In the first sunset review of each order, Commerce and the International Trade Commission (ITC) determined that continuation of each order was warranted.[2]

On February 5, 2019, Commerce initiated the current sunset reviews pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218.[3] We did not receive a notice of intent to participate from the domestic interested parties in either sunset review. As a result, in accordance with 19 CFR 351.218(d)(1)(iii)(A), Commerce has determined that no domestic interested party intends to participate in these sunset reviews. On February 21, 2019, in accordance with 19 CFR 351.218(d)(1)(iii)(B)(2), Commerce notified the ITC in writing that we intended to revoke the antidumping duty and countervailing duty orders on OTR Tires China.[4]

Scope of the Orders

The products covered by the orders are certain new pneumatic tires designed for off-the-road (OTR) and off highway use, subject to exceptions identified below. Certain OTR tires are generally designed, manufactured and offered for sale for use on off-road or off-highway surfaces, including but not

[1] *See Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Notice of Amended Final Affirmative Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 73 FR 51624 (September 4, 2008); *see also Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Countervailing Duty Order,* 73 FR 51627 (September 4, 2008).

[2] *See Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Continuation of Antidumping and Countervailing Duty Orders* 79 FR 6539 (February 4, 2014) (*Continuation Notice*).

[3] *See Initiation of Five-Year (Sunset) Reviews* 84 FR 1705 (February 5, 2019).

[4] *See Department Letter re: Sunset Review Initiated on February 5, 2019 Applicable to January 2019* (February 21, 2019).

limited to, agricultural fields, forests, construction sites, factory and warehouse interiors, airport tarmacs, ports and harbors, mines, quarries, gravel yards, and steel mills. The vehicles and equipment for which certain OTR tires are designed for use include, but are not limited to: (1) Agricultural and forestry vehicles and equipment, including agricultural tractors,[5] combine harvesters,[6] agricultural high clearance sprayers,[7] industrial tractors,[8] log-skidders,[9] agricultural implements, highway towed implements, agricultural logging, and agricultural, industrial, skid-steers/mini-loaders; [10] (2) construction vehicles and equipment, including earthmover articulated dump products, rigid frame haul trucks,[11] front end loaders,[12] dozers,[13] lift trucks, straddle carriers,[14] graders,[15] mobile cranes,[16] compactors; and (3) industrial vehicles and equipment, including smooth floor, industrial, mining, counterbalanced lift trucks, industrial and mining vehicles other than smooth floor, skid-steers/mini-loaders, and smooth floor off-the road counterbalanced lift trucks.[17] The foregoing list of vehicles and equipment generally have in common that they are used for hauling, towing, lifting, and/or loading a wide variety of equipment and materials in agricultural, construction and industrial settings. Such vehicles and equipment, and the descriptions contained in the footnotes are illustrative of the types of vehicles and equipment that use certain OTR tires but are not necessarily all-inclusive. While the physical characteristics of certain OTR tires will vary depending on the specific applications and conditions for which the tires are designed (*e.g.,* tread pattern and depth), all the tires within the scope have in common that they are designed for off-road and off-highway use. Except as discussed below, OTR tires included in the scope of the proceedings range in size (rim diameter) generally but not exclusively from 8 inches to 54 inches. The tires may be either tube-type 17 or tubeless, radial or non-radial, and intended for sale either to original equipment manufacturers or the replacement market. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.20.10.25, 4011.20.10.35, 4011.20.50.30, 4011.20.50.50, 4011.61.00.00, 4011.62.00.00, 4011.63.00.00, 4011.69.00.00, 4011.92.00.00, 4011.93.40.00, 4011.93.80.00, 4011.94.40.00, and 4011.94.80.00. While HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope is dispositive. Specifically excluded from the scope are new pneumatic tires designed, manufactured and offered for sale primarily for on-highway or on-road use, including passenger cars, race cars, station wagons, sport utility vehicles, minivans, mobile homes, motorcycles, bicycles, on-road or on-highway trailers, light trucks, and trucks and buses. Such tires generally have in common that the symbol ''DOT'' must appear on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Such excluded tires may also have the following designations that are used by the Tire and Rim Association:

Prefix letter designations:

- P—Identifies a tire intended primarily for service on passenger cars;
- LT—Identifies a tire intended primarily for service on light trucks; and,
- ST—Identifies a special tire for trailers in highway service. Suffix letter designations:
- TR—Identifies a tire for service on trucks, buses, and other vehicles with rims having specified rim diameter of nominal plus 0.156″ or plus 0.250″
- MH—Identifies tires for Mobile Homes;
- HC—Identifies a heavy duty tire designated for use on ''HC'' 15″ tapered rims used on trucks, buses, and other vehicles. This suffix is intended to differentiate among tires for light trucks, and other vehicles or other services, which use a similar designation.
- Example: 8R17.5 LT, 8R17.5 HC;
- LT—Identifies light truck tires for service on trucks, buses, trailers, and multipurpose passenger vehicles used in nominal highway service; and
- MC—Identifies tires and rims for motorcycles.

The following types of tires are also excluded from the scope: Pneumatic tires that are not new, including recycled or retreaded tires and used tires; non-pneumatic tires, including solid rubber tires; tires of a kind designed for use on aircraft, all-terrain vehicles, and vehicles for turf, lawn and garden, golf and trailer applications. Also excluded from the scope are radial and bias tires of a kind designed for use in mining and construction vehicles and equipment that have a rim diameter equal to or exceeding 39 inches. Such tires may be distinguished from other tires of similar size by the number of plies that the construction and mining tires contain (minimum of 16) and the weight of such tires (minimum 1500 pounds).

Revocation

Pursuant to section 751(c)(3)(A) of the Act and 19 CFR 351.218(d)(1)(iii)(B)(3), if no domestic interested parties respond to a notice of initiation, Commerce shall, within 90 days after the initiation of the review, revoke the order. Because no domestic interested party filed a notice of intent to participate in these sunset reviews, we are revoking the antidumping duty and countervailing duty orders on OTR Tires from China.

Effective Date of Revocation

Pursuant to sections 751(c)(3)(A) and 751(c)(6)(A)(iii) of the Act, and 19 CFR

[5] Agricultural tractors are dual-axle vehicles that typically are designed to pull farming equipment in the field and that may have front tires of a different size than the rear tires.

[6] Combine harvesters are used to harvest crops such as corn or wheat.

[7] Agricultural sprayers are used to irrigate agricultural fields.

[8] Industrial tractors are dual-axle vehicles that typically are designed to pull industrial equipment and that may have front tires of a different size than the rear tires.

[9] A log-skidder has a grappling lift arm that is used to grasp, lift and move trees that have been cut down to a truck or trailer for transport to a mill or other destination.

[10] Skid-steer loaders are four-wheel drive vehicles with the left-side drive wheels independent of the right-side drive wheels and lift arms that lie alongside the driver with the major pivot points behind the driver's shoulders. Skid-steer loaders are used in agricultural, construction and industrial settings.

[11] Haul trucks, which may be either rigid frame or articulated (*i.e.,* able to bend in the middle) are typically used in mines, quarries and construction sites to haul soil, aggregate, mined ore, or debris.

[12] Front loaders have lift arms in front of the vehicle. They can scrape material from one location to another, carry material in their buckets, or load material into a truck or trailer.

[13] A dozer is a large four-wheeled vehicle with a dozer blade that is used to push large quantities of soil, sand, rubble, etc., typically around construction sites. They can also be used to perform ''rough grading'' in road construction.

[14] A straddle carrier is a rigid frame, engine powered machine that is used to load and offload containers from container vessels and load them onto (or off of) tractor trailers.

[15] A grader is a vehicle with a large blade used to create a flat surface. Graders are typically used to perform ''finish grading.'' Graders are commonly used in maintenance of unpaved roads and road construction to prepare the base course onto which asphalt or other paving material will be laid.

[16] *I.e.,* ''on-site'' mobile cranes designed for off highway use.

[17] A counterbalanced lift truck is a rigid framed, engine-powered machine with lift arms that has additional weight incorporated into the back of the machine to offset or counterbalance the weight of loads that it lifts so as to prevent the vehicle from overturning. An example of a counterbalanced lift truck is a counterbalanced fork lift truck. Counterbalanced lift trucks may be designed for use on smooth floor surfaces, such as a factory or warehouse, or other surfaces, such as construction sites, mines, etc.

351.222(i)(2)(i), Commerce will instruct U.S. Customs and Border Protection to terminate the suspension of liquidation of the merchandise subject to these orders entered, or withdrawn from warehouse, on or after February 4, 2019, the fifth anniversary of the date of publication of the last continuation notice.[18] Entries of subject merchandise prior to the effective date of revocation will continue to be subject to suspension of liquidation and antidumping duty and countervailing duty deposit requirements. Commerce will complete any pending reviews of these orders and will conduct administrative reviews of subject merchandise entered prior to the effective date of revocation in response to appropriately filed requests for review.

These five-year (sunset) reviews, the revocation of the AD and CVD orders, and this notice are issued and published in accordance with sections 751(c)(3)(A) and 777(i)(1) of the Act and 19 CFR 351.218(d)(1)(iii)(B)(3).

Dated: May 6, 2019.

Jeffrey I. Kessler,

Assistant Secretary, for Enforcement and Compliance.

[FR Doc. 2019–09670 Filed 5–9–19; 8:45 am]

BILLING CODE 3510–DS–P

[18] *See Continuation Notice.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG332

Endangered Species; File No. 21858

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

ACTION: Notice; receipt of application for a permit modification.

SUMMARY: Notice is hereby given that NMFS Greater Atlantic Regional Fisheries Office (GARFO), 55 Great Republic Drive, Gloucester MA 01930 [Responsible Party: Julie Crocker], has requested a modification to scientific research Permit No. 21858.

DATES: Written, telefaxed, or email comments must be received on or before June 10, 2019.

ADDRESSES: The modification request and related documents are available for review by selecting ''Records Open for Public Comment'' from the Features box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 21858–03 from the list of available applications. These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427–8401; fax: (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. 21858 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Erin Markin or Jennifer Skidmore, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject modification to Permit No. 21858 is requested under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 21858, issued on September 7, 2018 (83 FR 53454), authorizes the permit holder to collect, receive, export, transport, and archive dead Atlantic (*Acipenser oxyrinchus*) and shortnose (*A. brevirostrum*) sturgeon, or parts thereof. This includes the receipt and export of 3,000 Atlantic and 1,500 shortnose sturgeon parts annually for the NMFS Sturgeon Tissue Repository. The permit holder requests authorization to increase the number of Atlantic and shortnose sturgeon samples from 3,000 to 15,000 and 1,500 to 5,000, respectively, to be received annually to the NMFS Sturgeon Tissue Repository. Intentional or incidental capture of Atlantic and shortnose sturgeon and collection of tissue samples occurs under separate authority. This permit does not authorize the capture and sampling of live specimens. The permit expires March 31, 2027.

Dated: May 6, 2019.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–09631 Filed 5–9–19; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes services previously furnished by such agencies.

DATES: Comments must be received on or before: June 09, 2019.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN—Product Name: MR 13033—Placemat, Woven, Assorted Colors
Mandatory Source of Supply: Chester County Branch of the PAB, Coatesville, PA
Contracting Activity: Military Resale-Defense Commissary Agency

NSN—Product Name: MR 1048—Bottle, Trigger, All Purpose, Opaque, 32 oz
Mandatory Source of Supply: Alphapointe, Kansas City, MO
Contracting Activity: Military Resale-Defense Commissary Agency

Service

Service Type: Mail Center Operations
Mandatory for: US Air Force, Arnold

Engineering Development Complex, Official Mail Center, Arnold Air Force Base, TN
Mandatory Source of Supply: CW Resources, Inc., New Britain, CT
Contracting Activity: DEPT OF THE AIR FORCE, FA9101 AEDC PKP PROCRMNT BR

Deletions

The following services are proposed for deletion from the Procurement List:

Services

Service Type: Contract Cook Support & Dining Facility Attendant
Mandatory for: White Sands Missile Range, NM
Mandatory Source of Supply: Tresco, Inc., Las Cruces, NM
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–WHITE SANDS

Service Type: Janitorial Services
Mandatory for: Norman Armed Force Reserve Center (AFRC), Norman, OK
Mandatory Source of Supply: Dale Rogers Training Center, Inc., Oklahoma City, OK
Contracting Activity: DEPT OF THE ARMY, W7NV USPFO ACTIVITY OK ARNG

Service Type: Janitorial Services
Mandatory for: Mustang Armed Force Reserve Center (AFRC), Mustang, OK
Mandatory Source of Supply: Dale Rogers Training Center, Inc., Oklahoma City, OK
Contracting Activity: DEPT OF THE ARMY, W7NV USPFO ACTIVITY OK ARNG

Service Type: Food Service Attendant
Mandatory for: Fort Custer Training Center, Augusta, MI
Mandatory Source of Supply: Calhoun County Community Mental Health Services, Battle Creek, MI
Contracting Activity: DEPT OF THE ARMY, W7NF USPFO ACTIVITY MI ARNG

Service Type: Packaging Service
Mandatory for: Crane Division, Naval Surface Warfare Center, Crane, IN
Mandatory Source of Supply: Knox County Association for Remarkable Citizens, Inc., Vincennes, IN
Contracting Activity: DEPT OF THE NAVY, US FLEET FORCES COMMAND

Service Type: Electronic Image Conversion
Mandatory for: Federal Bureau of Investigation: 9th & Pennsylvania Avenue NW, Washington, DC
Mandatory Source of Supply: ServiceSource, Inc., Oakton, VA
Contracting Activity: FEDERAL BUREAU OF INVESTIGATION, DEPT OF JUST/ FEDERAL BUREAU OF INVESTIGATION

Service Type: Mailroom Operation
Mandatory for: Defense Contract Management Agency, Barnes Building, 495 Summer St., Boston, MA
Mandatory Source of Supply: Community Workshops, Inc., Boston, MA
Contracting Activity: DEFENSE CONTRACT MANAGEMENT AGENCY (DCMA), DEFENSE CONTRACT MANAGEMENT AGENCY

Service Type: Janitorial/Custodial
Mandatory for: Rattlesnake National Recreation Area: Maclay Flat and Fort Fizzle, Missoula Ranger District, Missoula, MT
Mandatory Source of Supply: UNKNOWN
Contracting Activity: AGRICULTURE, DEPARTMENT OF, PROCUREMENT OPERATIONS DIVISION

Service Type: Administrative Services
Mandatory for: HUD Birmingham Field Office, Birmingham, AL
Mandatory Source of Supply: Nobis Enterprises, Inc., Marietta, GA
Contracting Activity: HOUSING AND URBAN DEVELOPMENT, DEPARTMENT OF, DEPT OF HOUSING AND URBAN DEVELOPMENT

Service Type: Janitorial/Custodial
Mandatory for: Social Security Administration, 190 Stone Street, Watertown, NY
Mandatory Source of Supply: Jefferson County Chapter, NYSARC, Watertown, NY
Contracting Activity: PUBLIC BUILDINGS SERVICE, GSA PBS R2 ACQUISITION MANAGEMENT DIVISION

Service Type: Janitorial/Custodial
Mandatory for: Social Security Administration Building, 517 N Barry Street, Olean, NY
Mandatory Source of Supply: Cattaraugus County Chapter, NYSARC, Olean, NY
Contracting Activity: PUBLIC BUILDINGS SERVICE, GSA PBS R2 ACQUISITION MANAGEMENT DIVISION

Service Type: Janitorial/Custodial
Mandatory for: Southeast Federal Center: M Street SE, Washington, DC
Mandatory Source of Supply: Davis Memorial Goodwill Industries, Washington, DC
Contracting Activity: PUBLIC BUILDINGS SERVICE, WPHBB—AGGREGATED REPAIR&ALTERATIONS CONTRACTS BRANCH

Service Type: Custodial service
Mandatory for: FEMA LA Recovery Office, Sherwood Forest Staging Area, 2695 Sherwood Forest, Baton Rouge, LA
Mandatory Source of Supply: Louisiana Industries for the Disabled, Inc., Baton Rouge, LA
Contracting Activity: FEDERAL EMERGENCY MANAGEMENT AGENCY, LOUISIANA CONTRACT OPS & MGMT BRANCH

Service Type: Custodial, Grounds Maintenance and Landscaping
Mandatory for: Cherokee National Forest-Tellico Ranger District, Tellico Plains, TN
Mandatory Source of Supply: Goodwill Industries—Knoxville, Inc., Knoxville, TN
Contracting Activity: AGRICULTURE, DEPARTMENT OF, AGRICULTURE, DEPARTMENT OF

Service Type: Disposal Support Services
Mandatory for: Gunter Air Force Base, AL
Mandatory Source of Supply: Goodwill Industries of Central Alabama, Inc., Montgomery, AL
Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA SUPPORT SERVICES—DSS

Service Type: Custodial service
Mandatory for: Southside Locust Pt Baltimore MD—CBP, Baltimore, MD
Mandatory Source of Supply: The Arc Baltimore, Inc., Baltimore, MD
Contracting Activity: U.S. CUSTOMS AND BORDER PROTECTION, PROCUREMENT DIRECTORATE

Service Type: Janitorial/Custodial
Mandatory for: U.S. Army Reserve Center: Westover Air Reserve Base, Chicopee, MA
Mandatory Source of Supply: Allied Community Services, Inc., Enfield, CT
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–FT DIX (RC–E)

Service Type: Janitorial Service
Mandatory for: Corpus Christi Resident Office, USACE (SAO), 1920 N Chaparral St., Corpus Christi, TX
Mandatory Source of Supply: Training, Rehabilitation, & Development Institute, Inc., San Antonio, TX
Contracting Activity: DEPT OF THE ARMY, W076 ENDIST GALVESTON

Service Type: Grounds Maintenance
Mandatory for: U.S. Army Reserve Center: 443 Route 119 North, Indiana, PA
Mandatory Source of Supply: UNKNOWN
Contracting Activity: DEPT OF THE ARMY, W40M RHCO–ATLANTIC USAHCA

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2019–09650 Filed 5–9–19; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes a product and services to the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date deleted from the Procurement List:* June 9, 2019.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 4/5/2019, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the product and services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product and services deleted from the Procurement List.

End of Certification

Accordingly, the following product and services are deleted from the Procurement List:

Product

NSN—Product Name: 3740–01–096–1632—Trap, Roach, Monitor
Mandatory Source of Supply: The Arc of Alachua County, Inc., Gainesville, FL
Contracting Activity: DLA AVIATION, RICHMOND, VA

Services

Service Type: Janitorial/Elevator Operator
Mandatory for: Southeast Federal Center: Buildings 159, 159E & 160, 2nd. & M Streets SE, Washington, DC
Mandatory Source of Supply: Davis Memorial Goodwill Industries, Washington, DC
Contracting Activity: DEPT OF THE NAVY, U.S. FLEET FORCES COMMAND

Service Type: Janitorial/Custodial
Mandatory for: Internal Revenue Service: 120 Church Street, New York, NY
Mandatory Source of Supply: Fedcap Rehabilitation Services, Inc., New York, NY
Contracting Activity: TREASURY, DEPARTMENT OF THE, DEPT OF TREAS/

Service Type: Janitorial/Custodial
Mandatory for: U.S. Army Reserve Center: Elkins, Beverly, WV
Mandatory Source of Supply: Buckhannon-Upshur Work Adjustment Center, Inc., Buckhannon, WV
Contracting Activity: DEPT OF THE ARMY, W40M RHCO-ATLANTIC USAHCA

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2019–09651 Filed 5–9–19; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0062]

Agency Information Collection Activities; Comment Request; FFEL/Direct Loan/Perkins Military Service Deferment/Post-Active Duty Student Deferment Request

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 9, 2019.

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–2019–ICCD–0062. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

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: FFEL/Direct Loan/Perkins Military Service Deferment/Post-Active Duty Student Deferment Request.

OMB Control Number: 1845–0080.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 16,000.

Total Estimated Number of Annual Burden Hours: 8,000.

Abstract: The Military Service/Post-Active Duty Student Deferment request form serves as the means by which a Federal Family Education Loan (FFEL), Perkins, or Direct Loan borrower requests a military service deferment and/or post-active duty student deferment and provides his or her loan holder with the information needed to determine whether the borrower meets the applicable deferment eligibility requirements. The form also serves as the means by which the U.S. Department of Education identifies Direct Loan borrowers who qualify for the Direct Loan Program's no accrual of interest benefit for active duty service members.

Dated: May 7, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–09688 Filed 5–9–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0061]

Agency Information Collection Activities; Comment Request; Direct Loan, FFEL, Perkins and TEACH Grant Total and Permanent Disability Discharge Application and Related Forms

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 9, 2019.

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–2019–ICCD–0061. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jon Utz, 202–377–4040.

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: Direct Loan, FFEL, Perkins and TEACH Grant Total and Permanent Disability Discharge Application and Related Forms.

OMB Control Number: 1845–0065.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 254,800.

Total Estimated Number of Annual Burden Hours: 127,400.

Abstract: The Discharge Application: Total and Permanent Disability serves as the means by which an individual who is totally and permanently disabled, as defined in section 437(a) of the Higher Education Act of 1965, as amended, applies for discharge of his or her Direct Loan, FFEL, or Perkins loan program loans, or TEACH Grant service obligation. The form collects the information that is needed by the U.S. Department of Education (the Department) to determine the individual's eligibility for discharge based on total and permanent disability. The Post-Discharge Monitoring: Total and Permanent Disability form serves as the means by which an individual who has received a total and permanent disability discharge provides the Department with information about his or her annual earnings from employment during the 3-year post-discharge monitoring period that begins on the date of discharge. The Applicant Representative Designation: Total and Permanent Disability form serves as the means by which an applicant for a total and permanent disability discharge may (1) designate a representative to act on his or her behalf in connection with the applicant's discharge request, (2) change a previously designated representative, or (3) revoke a previous designation of a representative.

Dated: May 7, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–09686 Filed 5–9–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Proposed Subsequent Arrangement

AGENCY: National Nuclear Security Administration, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Co-operation between the Government of the United States of America and the Swiss Federal Council Concerning the Peaceful Uses of Nuclear Energy.

DATES: This subsequent arrangement will take effect no sooner than May 28, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Oehlbert, Office of Nonproliferation and Arms Control, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–3806 or email: *sean.oehlbert@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This proposed subsequent arrangement concerns the addition of the United Kingdom of Great Britain and Northern Ireland (the United Kingdom) to the list of countries in Annex 1 of the Agreement for Co-operation between the Government of the United States of America and the Swiss Federal Council Concerning Peaceful Uses of Nuclear Energy, done at Berne on October 31, 1997 (the Agreement). Pursuant to paragraph B of the Agreed Minute to the Agreement, states or groups of states identified in Annex 1 to the Agreed Minute are eligible to receive retransfers from Switzerland of source material, low enriched uranium, moderator material, and equipment subject to Article 7 of the Agreement. The United Kingdom will be eligible to receive such retransfers upon entry into force of the Agreement between the Government of the United States of America and the

Government of the United Kingdom of Great Britain and Northern Ireland for Cooperation in Peaceful Uses of Nuclear Energy.

Pursuant to the authority in section 131 a. of the Atomic Energy Act of 1954, as delegated, I have determined that this proposed subsequent arrangement will not be inimical to the common defense and security of the United States of America.

Dated: April 30, 2019.

For the Department of Energy.

Brent K. Park,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2019–09679 Filed 5–9–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Proposed Subsequent Arrangement

AGENCY: National Nuclear Security Administration, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation between the Government of the United States of America and the Government of the Republic of Korea Concerning Peaceful Uses of Nuclear Energy.

DATES: This subsequent arrangement will take effect no sooner than May 28, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Oehlbert, Office of Nonproliferation and Arms Control, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–3806 or email: *sean.oehlbert@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This proposed subsequent arrangement concerns the addition of the United Kingdom of Great Britain and Northern Ireland (UK) to the advance consent list of countries or destinations referred to in paragraph 1(c) of Article 18 of the Agreement for Cooperation between the Government of the United States of America and the Government of the Republic of Korea Concerning Peaceful Uses of Nuclear Energy, done at Washington on June 15, 2015 (the Agreement) and paragraph 1.a. of section 3 of the Agreed Minute to the Agreement. Third countries or destinations on the advance consent list are eligible to receive retransfers from the Republic of Korea of unirradiated low enriched uranium, unirradiated source material, equipment and components subject to paragraph 2 of Article 10 of the Agreement. The UK will be eligible to receive such retransfers upon entry into force of the Agreement between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland for Cooperation in Peaceful Uses of Nuclear Energy.

Pursuant to the authority in section 131 a. of the Atomic Energy Act of 1954, as delegated, I have determined that this proposed subsequent arrangement will not be inimical to the common defense and security of the United States of America.

Dated: April 30, 2019.

For the Department of Energy.

Brent K. Park,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2019–09678 Filed 5–9–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

[DOE/EIS–0441]

Mohave County Wind Farm Project Record of Decision

AGENCY: Western Area Power Administration, DOE.

ACTION: Record of decision.

SUMMARY: NextEra Energy Resources, LLC (NextEra), through its entity Mohave County Wind Farm, LLC, proposes to develop its Mohave County Wind Farm Project (Project) and interconnect it to Western Area Power Administration's (WAPA) Mead-Peacock 345-kilovolt (kV) transmission line. The Project site is located in the White Hills of Mohave County, Arizona, on lands managed by the U.S. Department of Interior, Bureau of Land Management (BLM) and Bureau of Reclamation (Reclamation). Based in part on the analysis in the final environmental impact statement (Final EIS), WAPA has determined to allow NextEra's request for interconnection to WAPA's transmission system on the Mead-Peacock 345-kV transmission line; to construct, own, operate, and maintain a new Project switchyard and associated communications equipment; and to replace or upgrade certain equipment in the Mead Substation to accommodate the Project.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Mark Wieringa, NEPA Document Manager, Headquarters Office, Western Area Power Administration, A9402, P.O. Box 281213, Lakewood, CO 80228, telephone (720) 962–7448, or email *wieringa@wapa.gov.*

SUPPLEMENTARY INFORMATION: WAPA is a Federal agency within the Department of Energy (DOE) that markets and transmits wholesale electrical power through an integrated 17,000-circuit mile, high-voltage transmission system across 15 western states. WAPA's Open Access Transmission Service Tariff provides open access to its electric transmission system. In reviewing interconnection requests, WAPA must ensure that existing reliability and service are not degraded. WAPA's Large Generator Interconnection Procedures provides for transmission and system studies to ensure that system reliability and service to existing customers are not adversely affected by new interconnections.

In 2009, BP Wind Energy North America Inc. (BP Wind Energy) applied to the BLM and Reclamation for, respectively, right-of-way (ROW) and right-of-use (ROU) permits on public and Federal land to construct, operate, maintain, and eventually decommission a wind-powered electrical generation facility in Mohave County, Arizona. BP Wind Energy concurrently applied to interconnect its proposed Project to WAPA's Liberty-Mead 345-kV transmission line or the Mead-Phoenix 500-kV transmission line, of which WAPA is a participating partner, and both traverse the Project area in adjacent ROWs. The proposed Project site is located in the White Hills of Mohave County about 40 miles northwest of Kingman, Arizona, and immediately south of the Lake Mead National Recreation Area (NRA) boundary (map 1–1 of the Final EIS). The proposed Project is described in the Final EIS and is outlined in detail in the associated BLM Plan of Development (POD). These documents and others related to the proposed Project can be found on the BLM's website for the Project at *https://eplanning.blm.gov/epl-front-office/eplanning/legacyProjectSite.do?methodName=renderLegacyProjectSite&projectId=77804.*

In compliance with the National Environmental Policy Act (NEPA), as amended, and the Federal Land Policy and Management Act of 1976, as amended, the BLM as lead agency prepared and released a Draft EIS on April 27, 2012 (77 FR 25165), and subsequently held public meetings on

the document in Kingman, Dolan Springs, Peach Springs, and White Hills, Arizona, during the public comment period. WAPA was a cooperating agency in the NEPA process. Following the release of the Draft EIS, and with assistance from WAPA and other cooperating agencies, the BLM prepared a Final EIS that was released on May 17, 2013 (78 FR 29131). In addition to WAPA, other cooperating agencies involved in the Project included the U.S. Department of Interior, Bureau of Reclamation, Lower Colorado Region, and the National Park Service, Lake Mead National Recreation Area; the Hualapai Tribe, Department of Cultural Resources; the Arizona Game and Fish Department; and Mohave County, Arizona. After consideration of comments received on the Final EIS, the BLM and Reclamation approved the ROW and ROU grant on June 25, 2013, and signed a record of decision (ROD) on June 26, 2013. A Notice of Availability for the BLM ROD was published in the **Federal Register** on September 27, 2013 (78 FR 57173).

WAPA's Proposed Federal Action

At the time the Project was proposed, WAPA's proposed Federal action was to interconnect the Project to WAPA's existing Liberty-Mead 345-kV transmission line or the Mead-Phoenix 500-kV transmission line, of which WAPA is a participating partner, and to construct, own, operate, and maintain a new switchyard and communications facilities on BLM-administered public land adjacent to the transmission line. As a result of the original interconnection request, WAPA applied to the BLM for a ROW grant on the Project site to develop a switchyard on one of two approximately 10-acre locations that would interconnect the proposed wind generation Project to the electrical power grid; that ROW grant was approved as part of the grant to BP Wind Energy. WAPA also considered what upgrades to equipment in the Mead Substation would be required if the decision was to interconnect with the Liberty-Mead transmission line.

While the BLM concluded its NEPA process with their ROD and ROW grant in 2013, BP Wind Energy needed to secure contracts for the power resources to be generated by its proposed Project before it could determine the transmission path needed and to which of the two alternative transmission lines it wanted to interconnect. Selection of the transmission line would also determine which of the alternative substation/switchyard locations would be used. Because this decision was not made, WAPA could not execute a ROD at that time.

Subsequently the proposed Project was sold, and is currently being developed by NextEra. NextEra's entity developing the Project is still named Mohave County Wind Farm, LLC, but the Project itself has been renamed the White Hills Wind Project. In the interest of limiting confusion and retaining consistency with the prior NEPA documents, WAPA is using the original Mohave County Wind Farm Project name for purposes of this ROD.

NextEra has selected WAPA's Mead-Peacock 345-kV transmission line for interconnection, allowing WAPA to move forward with this ROD. Peacock Substation is located about halfway along the Mead-Liberty transmission line. The proposed Project remains within the same footprint, retains the same general turbine layout, and would generate the same amount of power, 425 megawatts (MW), as previously approved. Newer, more advanced turbine models are proposed, which would reduce the number of turbines compared to the original proposal. Preliminary engineering resulted in moving the Project substation and WAPA's switchyard east-southeast along the existing Mead-Peacock 345-kV transmission line about 0.9 miles to section 16, Township 28 North, Range 20 West. The new location will be surveyed for cultural and biological resources, and any change in impacts associated with this relocation, about 10 acres out of the 38,110 acres included in the Project site, is anticipated to be negligible.

NextEra has been coordinating with the BLM on their Project, and the BLM is aware of the Project changes. WAPA also consulted with the Arizona State Office of the BLM as a cooperating agency. The BLM has determined that there have been no substantial changes in the proposed action that are relevant to environmental concerns, and there are no significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts. Therefore, the BLM has determined that the Final EIS, BLM ROD, and BLM POD originally prepared for the BP Wind Energy Project remain valid and are fully adequate. Given the BLM's position, WAPA has determined that a Supplemental EIS is not required for its Federal action, which is a very small part of the overall Project.

The Proposed Project

The Project as originally proposed by BP Wind Energy and approved by BLM was to construct, operate, maintain, and eventually decommission a wind energy generation facility on BLM- and Reclamation-managed lands. The Project would generate and deliver electrical power to the regional electrical transmission grid by interconnecting with an existing transmission line crossing through the southern portion of the Project site. The Project's nameplate generating capacity would be 425 MW if the Project interconnected to the 345-kV Liberty-Mead transmission line and 500 MW if the Project interconnected to the 500-kV Mead-Phoenix transmission line.

Project features include, but are not limited to, turbines aligned within corridors, access roads, an operations and maintenance building, a water well drilled to support the operations and maintenance building, two temporary laydown/staging areas (with temporary concrete batch plant operations), temporary and permanent meteorological towers, two substations, the WAPA switchyard, and collector lines that carry the power from the turbines to the substations. While typically buried underground, collector lines could be on aboveground structures to span terrain and environmentally and culturally sensitive areas. The Project would require:

- Up to 10 acres of BLM-administered public lands within the Project site to be used for construction of the switchyard that will be operated by WAPA;
- An approximately 3-mile long access road between the Project site and U.S. Route 93 (US 93);
- Temporary use of the existing Detrital Wash Materials Pit as a materials source for the base material of roads and for concrete needed for foundations. The existing water wells in the immediate vicinity of this materials source would provide temporary construction-phase water for batch plant operations and dust suppression;
- A temporary water pipeline that would extend within the primary access road ROW from the materials source to the main laydown/staging area where batch plant operations would occur;
- A distribution line that would tap into an existing power line south of the Project site, parallel US 93 north to the access road, follow the access road to the main (southernmost) laydown/staging area where batch plant operations will occur, and extend to the operations and maintenance building; and
- Replacement of an existing 345/230-kV transformer and associated breakers and switches within WAPA's Mead Substation with two new 600 megavolt-ampere (MVA) 345/230-kV

transformers and new breakers and switches if the 345-kV interconnection option is selected. These replacements, which would be required to accommodate the increased electrical loading related to generation from the proposed Project, would be accomplished by WAPA at BP Wind Energy's expense. The existing transformer is at the terminus of the Liberty-Mead 345-kV line in Mead Substation; the substation is located near Boulder City, Nevada.

BP Wind Energy filed applications to interconnect the Project described above with either the 345-kV or 500-kV transmission line in 2009. NextEra's current Project would also be as described above, except that the substation and adjacent WAPA switchyard location have been relocated, fewer turbines would be constructed, and the Project would interconnect to the Mead-Peacock portion of the Mead-Liberty 345-kV transmission line. Some of the equipment in Mead Substation slated for replacement as part of the Project has already been upgraded during the 2013–2018 time frame, but one transformer and associated equipment would still have to be replaced as part of the Project, as well as some communications work.

Description of Project Alternatives

Five alternatives were considered in the Final EIS. Alternative A was the proposed action identified by BP Wind Energy. Alternative B reduced the proposed Project site footprint and would have fewer turbines than Alternative A to reduce visual and noise impacts primarily on Lake Mead NRA and secondly on private property. Alternative C also reduced the proposed Project site footprint and had fewer turbines than Alternative A to reduce visual and noise impacts. Alternative D was the no-action alternative under which the proposed Project would not be built. Alternative E (Preferred Alternative) was a combination of Alternatives A and B and responds to concerns for visual and noise impacts on Lake Mead NRA and existing residents. Alternative E also addressed information about golden eagle breeding areas, which supported the need to establish a no-build area and curtailment zone to reduce potential impacts on golden eagles within the Squaw Peak breeding area in the northwest portion of the Project site. All action alternatives included the Project features as described above under ''The Proposed Project.'' NextEra plans to implement Alternative E.

WAPA, the BLM, and Reclamation determined that the No Action Alternative and Alternative E, the Selected Alternative, were the environmentally preferred alternatives because they will cause the least damage to the biological and physical environment. Although the No Action Alternative would have the least effect on the environment, the No Action Alternative would not allow development of the proposed Project and would not meet the BLM's and Reclamation's purpose and need for Federal action, including responding to BP Wind Energy's (now NextEra's) application for ROW and ROU permits and furthering national renewable energy policies and directives, nor would it meet WAPA's purpose and need for responding to the interconnection request and providing open access to transmission in accordance with Federal law. Of the action alternatives, the Selected Alternative represents the environmentally preferred alternative because it meets the various agencies' purpose and need for Federal action, assists in meeting Federal and state renewable energy goals and reduces greenhouse gas emissions, includes measures to protect golden eagles and other biological resources, effectively minimizes potential visual and noise effects on the Lake Mead NRA by eliminating selected turbine corridors in the northwest and northeast portions of the Project area, and requires a minimum 0.25-mile setback from private land to reduce potential visual and noise effects. The phased approach to development and curtailment zone will emphasize initial development in less environmentally sensitive areas and minimize impacts to nesting golden eagles.

Description of WAPA Switchyard Location Options

The construction portion of WAPA's proposed Federal action is limited to about 10 acres within the overall approximately 38,110-acre Project site. The Project alternatives ultimately developed by the BLM and Reclamation were primarily variations of turbine string arrangements within the same general location. Existing transmission lines that BP Wind Energy initially considered for interconnection included the Liberty-Mead 345-kV transmission line, the Mead-Phoenix 500-kV transmission line, and the Moenkopi-El Dorado 500-kV transmission line, with the latter line being dropped for consideration during the NEPA process. The Liberty-Mead and Mead-Phoenix lines parallel each other on adjacent ROWs and pass through the Project site. WAPA and the other agencies considered suitable switchyard and adjacent Project substation locations along these lines, with potential 500-kV interconnection locations located on the north of the lines and 345-kV locations on the south, adjacent to their respective voltage lines. Once determined, these locations were the same for all proposed Project action alternatives.

Two switchyard locations east of the Project site were considered for an interconnection to the Mead-Phoenix 500-kV transmission line during the preparation of the electrical system studies. These two interconnection points were considered when a solar-powered generation facility was proposed east of the Project. A shared interconnection point located between the two proposed projects was proposed, but the solar project was cancelled, eliminating the need for a shared interconnection. Therefore, these two off-site interconnection points and the additional transmission required to reach them were dropped from further consideration.

Three locations were identified for the 345-kV switchyard within the Project site, each paired with a nearby Project substation location (one of two substations planned for the proposed Project). The locations each had at least 10 acres that could be developed and were relatively level. Besides proximity to the Liberty-Mead transmission line, locations were also selected based on the proposed layout of Project facilities, lack of identified cultural resources, lack of listed plant species, minimal presence of sensitive plant species, presence of existing site access, and a lack of near-surface rock or rock outcrops that would complicate grading and construction.

These criteria, plus consideration of the proposed Project substation location, led to the elimination of two of the locations, and incorporation of the best-suited switchyard location into the Project action alternatives. The same process was used to identify and select the 500-kV switchyard location on the north side of the two existing transmission lines, which also became part of the larger Project alternatives. These locations were sited in sections 8 and 9 of Township 28 North, Range 20 West for the 345-kV and 500-kV interconnection points, respectively. Of the locations identified, these switchyard locations were determined to be the locations having the least potential environmental impact. Subsequently, initial design work for the NextEra Project resulted in the identification of a new location for the

Project substation and adjacent WAPA switchyard in section 16 of Township 28 North, Range 20 West, on the south side of the parallel transmission lines. Visits to the original location resulted in the identification of potential jurisdictional waters due to the washes and erosional features present. The new location avoids jurisdictional waters and related washes and has favorable slopes and elevation. The new location would require less grading and avoids the need to re-direct active washes, so overall environmental impacts are expected to be reduced when compared to the original location.

Mitigation Measures

Since the WAPA switchyard is an integral component of the Project, it will be subject to the applicable mitigation measures identified in the BLM's ROD under 4.0 Mitigation Measures, chapter 4 of the Final EIS, the Project POD, and the Project and WAPA's ROW grant. The BLM also has a series of specific plans addressing particular aspects of the Project, including an Integrated Reclamation Plan; Health, Safety, Security, and Environment Plan; Spill Prevention, Control, and Countermeasure Plan; Transportation and Traffic Plan; Dust and Emissions Control Plan; Blasting Plan (if required); Mining Plan of Operations; Flagging Plan; Decommissioning Plan; Eagle Conservation Plan/Bird Conservation Strategy; Bat Conservation Strategy; Stormwater Pollution Prevention Plan; and Environmental Construction Compliance and Monitoring Plan. Specific measures for the switchyard in the ROW grant from the BLM, if any, will also be implemented. In addition, best management practices and construction requirements included in WAPA's Construction Standard 13 will be in effect for the switchyard, and enforced through a mandatory clause in the switchyard construction contract. As the switchyard location will be graded flat and covered with aggregate, environmental concerns are mostly related to dust abatement, stormwater control, and erosion prevention. WAPA's design for and construction of the switchyard will anticipate these potential impacts and avoid or minimize them so additional mitigation is not required. The various plans, requirements, and mitigations discussed above incorporate all practicable means to avoid or minimize environmental harm from the proposed Project.

Comments on the Final EIS

The BLM received comments on the Final EIS from the U.S. Environmental Protection Agency and the National Park Service, among others. None of these comments raised substantive issues requiring a response, but were considered in the BLM's and Reclamation's decision making. Additionally, Defenders of Wildlife provided recommendations to the U.S. Fish and Wildlife Service regarding the Eagle Conservation Plan. None of the comments received on the Final EIS were specific to WAPA's switchyard. WAPA determined that the comments did not present any significant new circumstances or information relevant to environmental concerns and bearing on the Project or its impacts, and a Supplemental EIS was not required.

Decision

WAPA's decision is to allow NextEra's request for interconnection to WAPA's Mead-Peacock 345-kV transmission line; to construct, own and operate a new switchyard; and to replace or upgrade certain equipment within the existing Mead Substation at NextEra's expense. WAPA's decision to grant this interconnection request satisfies the agency's statutory mission and NextEra's objectives and is consistent with the BLM's and Reclamation's decisions while minimizing harm to the environment. Full implementation of this decision is contingent upon NextEra meeting all BLM and Reclamation requirements and obtaining all other applicable permits and approvals as well as executing an interconnection agreement in accordance with WAPA's Open Access Transmission Service Tariff.

This decision is based on the information contained in the Mohave County Wind Farm Project Draft and Final EIS, BLM's ROD, BLM's POD, recent coordination with the BLM's Arizona State Office, and WAPA's updated interconnection facilities study. This ROD was prepared pursuant to the requirements of the Council on Environmental Quality Regulations for Implementing NEPA (40 CFR parts 1500–1508) and DOE's Procedures for Implementing NEPA (10 CFR part 1021).

Dated: April 29, 2019.

Mark A. Gabriel,

Administrator.

[FR Doc. 2019–09677 Filed 5–9–19; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9044–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/*.

Weekly receipt of Environmental Impact Statements

Filed 04/29/2019 Through 05/03/2019

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search*.

EIS No. 20190085, Final, FERC, AK, Grant Lake Hydroelectric Project, Review Period Ends: 06/10/2019, Contact: Office of External Affairs 866–208–3372.

EIS No. 20190086, Final, USACE, CO, Adams and Denver Counties, Colorado General Investigation Study, Review Period Ends: 06/10/2019, Contact: Dave Crane 402–995–2676.

EIS No. 20190087, Final, NASA, VA, NASA WFF Site-wide Programmatic Environmental Impact Statement, Review Period Ends: 06/10/2019, Contact: Shari A. Miller 757–824–2327.

EIS No. 20190088, Draft, USACE, CA, Draft Integrated General Reevaluation Report and Environmental Impact Statement for San Francisco Bay to Stockton, California Navigation Study, Comment Period Ends: 06/24/2019, Contact: Stacie Auvenshine 904–314–7614.

EIS No. 20190089, Final, NPS, CA, Saline Valley Warm Springs Management Plan, Review Period Ends: 06/10/2019, Contact: Kelly Daigle 303–987–6897.

EIS No. 20190090, Final, BR, CA, Central Valley Project Water Supply Contracts Under Public Law 101–514 (Section 206): Contract Between the U.S. Bureau of Reclamation and the El Dorado County Water Agency, Subcontract Between the El Dorado County Water Agency and the El Dorado Irrigation District, and Subcontract Between the El Dorado County Water Agency and the Georgetown Divide Public Utility District, Review Period Ends: 06/10/2019, Contact: Cynthia Meyer 916–537–7060.

EIS No. 20190091, Final, FERC, LA, Plaquemines LNG and Gator Express Pipeline Project, Review Period Ends: 06/10/2019, Contact: Office of External Affairs 866–208–3372.

EIS No. 20190092, Final Supplement, USACE, AL, Mobile Harbor, Mobile, Alabama Integrated Final General Evaluation Report with Supplemental Environmental Impact Statement, Review Period Ends: 06/10/2019, Contact: Jennifer L. Jacobson 251–690–2724.

EIS No. 20190093, Final, USACE, CA, Whittier Narrows Dam Flood Control Project Dam Safety Modification Study, Review Period Ends: 06/10/2019, Contact: Deborah Lamb 213–452–3798.

EIS No. 20190094, Final, BLM, CA, Central Coast Field Office Proposed Resource Management Plan Amendment and Final Environmental Impact Statement for Oil and Gas Leasing and Development, Review Period Ends: 06/10/2019, Contact: Sky Murphy 831–582–2231.

EIS No. 20190095, Final, FHWA, SC, Carolina Crossroads I–20/26/126 Corridor Improvement Project, Contact: Jeffrey S. Belcher 803–253–3187. Under 23 U.S.C. 139(n)(2), FHWA has issued a single document that consists of a final environmental impact statement and record of decision. Therefore, the 30-day wait/review period under NEPA does not apply to this action.

Amended Notice

EIS No. 20180168, Draft, USACE, AL, Mobile Harbor, Mobile, Alabama Draft Integrated General Reevaluation Report with Supplemental Environmental Impact Statement, Comment Period Ends: 09/10/2018, Contact: Jennifer L. Jacobson 251–690–2724 Revision to FR Notice Published 07/27/2018; Correction to Document Type from Draft to Draft Supplemental.

EIS No. 20190060, Draft, USFWS, CA, Proposed Habitat Conservation Plan and Incidental Take Permit for Sierra Pacific Industries, Comment Period Ends: 07/01/2019, Contact: Kim Turner 916–414–6600. Revision to FR Notice Published 04/19/2019; Extending the Comment Period from 06/18/2019 to 07/01/2019.

EIS No. 20190082, Draft Supplement, BLM, AK, Supplemental Draft Environmental Impact Statement for the Haines Amendment to the Ring of Fire Resource Management Plan, Comment Period Ends: 08/01/2019, Contact: Marnie Graham 907–822–3217. Revision to FR Notice Published 05/03/2019; Correcting the Comment Period from 07/25/2019 to 08/01/2019.

Dated: May 6, 2019.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2019–09547 Filed 5–9–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2019–0194; FRL9993–29–OLEM]

Hazardous Waste Electronic Manifest System (''e-Manifest'') Advisory Board; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) will convene the Hazardous Waste Electronic System (''e-Manifest'') Advisory Board for a three (3) day public meeting to seek the Board's consultation and recommendations regarding the e-Manifest system (Meeting Theme: ''*Increasing Adoption of the e-Manifest System*'').

DATES: The meeting will be held on June 18–20, 2019, from approximately 9:00 a.m. to 5:00 p.m. EDT.

Comments. The Agency encourages written comments be submitted on or before June 4, 2019, and requests for oral comments to be submitted on or before June 11, 2019. Written comments and requests to make oral comments may be submitted up until the date of the meeting; however, anyone submitting written comments or requests for oral comments after June 11, 2019, should contact the Designated Federal Officer (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see section I.C. under **SUPPLEMENTARY INFORMATION**.

Webcast. This meeting may be webcast. Please refer to the e-Manifest website at *www.epa.gov/e-manifest* for information on how to access the webcast. Please note that the webcast is a supplementary public service provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least ten (10) days prior to the meeting to give the EPA as much time as possible to process your request.

ADDRESSES:

Meeting: The meeting will be held at the Environmental Protection Agency Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S Crystal Dr., Arlington, VA 22202.

Comments. Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2019–0194 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*e.g.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Fred Jenkins, Designated Federal Officer (DFO), U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5303P), 1200 Pennsylvania Avenue NW, Washington, DC, 20460, Phone: 703–308–7049; or by email: *jenkins.fred@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of particular interest to persons who are or may be subject to the Hazardous Waste Electronic Manifest Establishment (e-Manifest) Act.

B. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this document. To ensure proper receipt of your public comments by the EPA, it is imperative that you identify docket ID number EPA–HQ–OLEM–2019–0194.

1. *Written comments.* The Agency encourages written comments be

submitted electronically via *regulations.gov,* using the instructions in the **ADDRESSES** *Comments* section on or before June 4, 2019, to provide the e-Manifest Advisory Board the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after June 11, 2019, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring fifteen (15) copies for distribution to the e-Manifest Advisory Board.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to the e-Manifest Advisory Board to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before June 11, 2019, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting. To the extent that time permits, the Chair of the e-Manifest Advisory Board may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) that the individual represents, and any requirements for audiovisual equipment. Oral comments before the e-Manifest Advisory Board are limited to approximately five (5) minutes unless prior arrangements have been made. In addition, each speaker should bring fifteen (15) copies of his or her comments and presentation for distribution to the e-Manifest Advisory Board at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

C. Purpose of the e-Manifest Advisory Board

The Hazardous Waste Electronic Manifest System Advisory Board is established in accordance with the provisions of the Hazardous Waste Electronic Manifest Establishment Act, 42 U.S.C. 6939g, and the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2. The e-Manifest Advisory Board is in the public interest and supports the Environmental Protection Agency in performing its duties and responsibilities.

The e-Manifest Advisory Board will provide recommendations on matters related to the operational activities, functions, policies, and regulations of the EPA under the e-Manifest Act, including: The effectiveness of the e-Manifest IT system and associated user fees and processes; matters and policies related to the e-Manifest program; regulations and guidance as required by the e-Manifest Act; actions to encourage the use of the electronic (paperless) system; changes to the user fees as described in e-Manifest Act Section 2(c)(3)(B)(i); and issues in the e-Manifest area, including those identified in the EPA's E-Enterprise strategy that intersect with the e-Manifest system, such as: Business-to-business communications; performance standards for mobile devices; and the EPA's Cross Media Electronic Reporting Rule (CROMERR) requirements.

The sole duty of the Advisory Board is to provide advice and recommendations to the EPA Administrator. As required by the e-Manifest Act, the e-Manifest Advisory Board is composed of nine (9) members. One (1) member is the EPA Administrator (or a designee), who serves as Chairperson of the Advisory Board. The rest of the committee is composed of:

- At least two (2) members who have expertise in information technology;
- At least three (3) members who have experience in using or represent users of the manifest system to track the transportation of hazardous waste under the e-Manifest Act;
- At least three (3) members who are state representatives responsible for processing manifests.

All members of the e-Manifest Advisory Board, except for the EPA Administrator, are appointed as Special Government Employees or representatives.

D. Public Meeting

EPA launched the e-Manifest system on June 30, 2018. e-Manifest enables those persons required to use a RCRA manifest under either federal or state law the option of using electronic manifests to track shipments of hazardous waste and to meet certain RCRA reporting and recordkeeping requirements.

EPA will convene its next public meeting of the e-Manifest System Advisory Board from June 18–20, 2019. The purpose of this meeting is to obtain advice from the Board on ways to increase the adoption of the e-Manifest system. The Agency has received feedback from the user community that clarifying the requirements and implementation of CROMERR is one way to encourage greater adoption of fully electronic manifests. The Agency will address this topic and propose technological solutions for consideration by the Board.

E. e-Manifest Advisory Board Documents and Meeting Minutes

The meeting background paper, related supporting materials, charge/questions to the Advisory Board, the Advisory Board membership roster (*i.e.,* members attending this meeting), and the meeting agenda will be available by approximately mid-May 2019. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available at *http://www.regulations.gov* and the e-Manifest Advisory Board website at: *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board*.

The e-Manifest Advisory Board will prepare meeting minutes summarizing its recommendations to the Agency approximately ninety (90) days after the meeting. The meeting minutes will be posted on the e-Manifest Advisory Board website or may be obtained from the docket at *http://www.regulations.gov*. Regarding the e-Manifest Advisory Board membership, prior to this meeting, EPA will announce the full membership of the Board including newly appointed and/or reappointed members on the e-Manifest Advisory Board web page at *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board*.

Dated: April 24, 2019.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery, Office of Land and Emergency Management.

[FR Doc. 2019–09693 Filed 5–9–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 19–274]

Consumer Advisory Committee; Meeting

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission announces the renewal of its Consumer Advisory Committee (CAC or Committee) and announces the next meeting date, time, and agenda of the Committee.

DATES: June 3, 2019. The meeting will come to order at 9:00 a.m.

ADDRESSES: Federal Communications Commission, 445 12th Street SW,

Commission Meeting Room TW–C305, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Scott Marshall, Designated Federal Officer of the Committee, (202) 418–2809 (voice or Relay); email *Scott.Marshall@fcc.gov.*

SUPPLEMENTARY INFORMATION: By Public Notice (DA 19–274) dated and released April 10, 2019, the Commission announced renewal of the Committee's charter now in its tenth term ending October 20, 2020. This renewal is necessary and in the public interest.

Proposed Agenda: At its June 3, 2019 meeting, the CAC is expected to discuss the roles and responsibilities of the Committee and its members, issues that the Commission wishes the Committee to address, meeting schedules, and any other topics relevant to the CAC's work. The CAC may also receive briefings from Commission staff on issues of interest to consumers.

This meeting is open to members of the general public. The FCC will accommodate as many participants as possible; however, admission will be limited to seating availability. The Commission will also provide audio and/or video coverage of the meeting over the internet from the FCC's web page at: *www.fcc.gov/live.* Oral statements at the meeting by parties or entities not represented on the CAC will be permitted to the extent time permits, at the discretion of the CAC Chair and the DFO. Members of the public may submit comments to the CAC in the FCC's Electronic Comment Filing System, ECFS, at: *www.fcc.gov/ecfs.*

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to: *fcc504@fcc.gov* or by calling the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please include a way for the FCC to contact the requester if more information is needed to fill the request. Please allow at least five days' advance notice; last minute requests will be accepted but may not be possible to accommodate.

Gregory Haledjian,

Legal Advisor, Consumer and Governmental Affairs Bureau.

[FR Doc. 2019–09668 Filed 5–9–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 201299.

Agreement Name: Sealand/GWF Reciprocal Slot Charter Agreement.

Parties: Maersk Line A/S DBA Sealand and Great White Fleet Liner Services Ltd.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Agreement authorizes the parties to charter space to/from one another in the trade between the Atlantic Coast of Florida and the U.S. Gulf Coast on the one hand and ports in Guatemala, Honduras, Costa Rica, and Panama on the other hand.

Proposed Effective Date: 6/15/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/22394.

Agreement No.: 201300.

Agreement Name: CMA CGM/Marfret Vessel Sharing Agreement Mediterranean—Caribbean/U.S. Gulf.

Parties: Compagnie Maritime Marfret S.A.S. and CMA CGM S.A.

Filing Party: Draughn Arbona; CMA CGM (America) LLC.

Synopsis: The Agreement authorizes CMA CGM and Marfret to cooperate on the provision of a weekly liner service in the Trade between Italy, France, Spain, the French Indies, the Dominican Republic, Colombia, Mexico, Costa Rica, Panama and the U.S. Gulf Coast.

Proposed Effective Date: 5/6/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/22395.

Dated: May 7, 2019.

Rachel Dickon,

Secretary.

[FR Doc. 2019–09694 Filed 5–9–19; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Temporary Suspension of Dogs Entering the United States From Egypt

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces that, effective immediately, it is temporarily suspending the importation of dogs from Egypt. This includes dogs originating in Egypt that are imported from third-party countries if the dogs have been present in those countries for less than six months. CDC is taking this action in response to an increase of imported cases of rabies in dogs from Egypt. This action is needed to prevent the reintroduction of canine rabies virus variant (CRVV), which has been eliminated from the United States. This suspension will remain in place until appropriate veterinary controls have been established in Egypt to prevent the export of rabid dogs. CDC will coordinate with other federal agencies and entities as necessary to implement this action.

DATES: This notice is applicable May 10, 2019.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice contact: Ashley A. Altenburger, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H16–4, Atlanta, GA 30329.

For information regarding CDC operations related to this notice contact: Kendra Stauffer, D.V.M., Division of Global Migration and Quarantine, Centers for Disease Control and-Prevention, 1600 Clifton Road NE, MS–V–18–2, Atlanta, GA 30329. Either person may also be reached by telephone 404–498–1600 or email *CDCAnimalImports@cdc.gov.*

SUPPLEMENTARY INFORMATION

I. Background

Rabies, one of the deadliest zoonotic diseases, accounts for an estimated 59,000 human deaths globally each year [1]—which equates to one human

[1] Hampson K, Coudeville L, Lembo T, et al. Estimating the global burden of endemic canine rabies. PLoS Negl Trop Dis 2015;9:e0003709.

death every 9 minutes. The virus can infect any mammal, and once clinical signs appear, the disease is usually fatal.[2] In September 2007, at the Inaugural World Rabies Day Symposium, HHS/CDC declared the United States to be free of canine rabies virus variant (CRVV). However, this rabies virus variant remains a serious public health threat in many other countries where laboratory and epidemiologic surveillance for CRVV is not as strong as in the United States. Many other countries also do not maintain a robust rabies vaccination program for dogs. Preventing the entry of animals infected with CRVV into the United States is a public health priority. Globally, CRVV is responsible for 98% of the estimated 59,000 human rabies deaths worldwide each year (WHO, 2004 [Page 116]).

On January 29, 2019, a shipment of 26 dogs was imported from Egypt to the United States through Canada by a Kansas-based rescue organization. All 26 dogs were placed into foster care or adopted in the Kansas City metro area of Kansas and Missouri. On February 25, 2019, one of the imported dogs, after biting a veterinary technician and exhibiting signs of illness, tested positive for rabies. Testing performed at CDC revealed that the rabid dog was infected with CRVV. Molecular characterization of the rabies virus also determined that it was most similar to a clade (group of organisms with a common ancestor) found in Egypt. This laboratory testing confirms that the dog was infected in Egypt prior to arrival in the United States.

Official notification of this event was made to the appropriate Egyptian ministry officials through the World Health Organization (WHO) International Health Regulation (IHR) rabies national focal point, the World Organization for Animal Health (OIE) delegate to Egypt, and through the CDC country office in Egypt. OIE develops guidance for importation requirements of animals, control of rabies in animals, and oversees an OIE member country's self-declaration of rabies-free status. It can revoke a country's self-declaration of rabies-free status and make notifications to OIE member countries if it is concerned about a threat to animal health.

This incident is the most recent example of cases of rabies in dogs imported from Egypt that have occurred in the last four years. On May 30, 2015, a shipment of 8 dogs and 27 cats arrived at John F. Kennedy (JFK) International Airport in New York City from Cairo, Egypt. The animals were distributed in New Jersey, Pennsylvania, Maryland, and Virginia to several animal rescue groups and one permanent adoptive home. On May 31, 2015, four dogs from the shipment were further distributed to three foster homes in Virginia that were connected with a Virginia-based rescue group.

On June 3, 2015, an adult female stray dog imported by an animal rescue group as part of this shipment became ill. The dog had been imported with an unhealed fracture of the left forelimb and 4 days after arriving at a foster home in Virginia developed clinical signs consistent with rabies. Because of concern about rabies, a veterinarian euthanized the dog on June 5, 2015, and submitted brain tissue for rabies testing. On June 8, 2015, the Virginia Department of General Services Division of Consolidated Laboratory Services confirmed rabies infection by laboratory testing. A tissue sample was sent to CDC for further testing (*i.e.,* molecular characterization), which can help determine where the rabies virus originated. Testing performed at CDC revealed that the rabid dog was infected with CRVV, and molecular characterization of the rabies virus determined that it was most similar to a clade found in Egypt.[3] This laboratory testing confirms that the dog was infected in Egypt prior to arrival in the United States.

On December 20, 2017, a shipment of four dogs exported by a U.S.-based animal rescue group in Cairo, Egypt arrived at JFK. Two transporters and one owner retrieved the dogs, with planned distribution to foster homes and permanent owners in Connecticut, Maryland, and Virginia. A fifth dog on the flight was temporarily housed in New Jersey and West Virginia before reaching its destination in Washington State. This dog was traveling with a separate handler and was not part of the shipment, but shared the cargo hold with other animals.

On December 21, 2017, one of the four dogs exhibited hyperesthesia (increased sensitivity to stimuli) and paresis (muscle weakness) upon assessment at a Connecticut veterinary clinic. The dog bit a veterinary technician during a blood draw procedure and died shortly thereafter. On December 26, 2017, the Connecticut Department of Public Health Laboratory confirmed rabies virus infection by laboratory testing. On December 28, 2017, testing performed at CDC revealed that the rabid dog was infected with CRVV and molecular characterization of the rabies virus determined that it was most similar to a clade found in Egypt. This laboratory testing confirms that the dog was infected in Egypt prior to arrival in the United States.

Staff members with the state health department interviewed dog caretakers, volunteers, and employees associated with the involved rescue groups and veterinary hospital staff members for potential exposure to rabid dogs in all three cases. Post-exposure prophylaxis was recommended and administered to those individuals considered exposed. No human rabies cases nor dog-to-dog transmission cases resulted due to prompt diagnosis and public health interventions.

II. Public Health Rationale

A person usually becomes infected with rabies through the bite of a rabid animal. Once a person is bitten by a rabid animal, the virus enters the wound and travels through the nerves to the spinal cord and brain. It is also possible, but quite rare, for a person to become infected through infectious material from a rabid animal, such as saliva, contacting a person's eyes, nose, mouth, or a wound. The incubation period for rabies is generally between 3–12 weeks, and during this time, the person may show no signs of illness. Once symptoms appear, the person typically dies within 1–2 weeks because rabies is almost 100% fatal in humans that are not treated before the onset of clinical signs. No treatment has been found to be routinely effective after clinical signs of disease begin. Investigations into potential exposures from the import of a rabid dog can be long, difficult and expensive.[4]

The United States was declared CRVV free in 2007. The importation of just one dog infected with CRVV risks the re-introduction of the virus into the United States. CRVV has been highly successful at adapting to new host species, particularly wildlife. Importation of even one CRVV-infected dog could result in transmission to humans, transmission to other dogs, transmission to wildlife, and of particular concern, could result in sustained transmission in a susceptible animal population, thereby threatening our entire rabies

[2] Fooks AR, Banyard AC, Horton DL, Johnson N, McElhinney LM, Jackson AC. Current status of rabies and prospects for elimination. Lancet 2014;384:1389–99.

[3] Sinclair JR, Wallace RM, Gruszynski K, et al. Rabies in a dog imported from Egypt with a falsified rabies vaccination certificate—Virginia, 2015. MMWR Morb Mortal Wkly Rep 2015;64:1359–62.

[4] Hercules Y, Bryant NJ, Wallace RM, et al. Rabies in a Dog Imported from Egypt—Connecticut, 2017. MMWR Morb Mortal Wkly Rep 2018;67:1388–1391. DOI: *http://dx.doi.org/10.15585/mmwr.mm6750a3.*

public health infrastructure. While CDC estimates that each year 100,000 dogs are imported from various high-risk CRVV countries, since 2015, three rabid dogs have been imported into the United States, and all were from Egypt.

To date, CDC efforts to work with Egyptian officials have proven unsuccessful at identifying root causes of these importation events and at identifying satisfactory solutions to reduce the risk of exportation of CRVV from Egypt. Egyptian officials failed to respond to requests for information pertaining to actions taken to prevent further export of rabies-infected dogs. In order to protect the public from rabies risk when the paperwork used to import a rabies-infected dog is suspected or confirmed to be fraudulent, good public health practice warrants appropriate follow-up that entails investigation of the responsible veterinarian or organization and possible revocation of license if fraud is proven. Egyptian officials have thus far not provided information as to whether this type of investigation and response have occurred. Similarly, in instances of suspected vaccination failures, appropriate follow-up by Egyptian officials to protect public health should include investigation of vaccine quality, the distribution chain, cold-chain maintenance, and inoculation methods. Egyptian officials, contrary to International Health Regulations and responsibilities, have thus far not provided information as to whether an investigation into the quality and management of animal rabies vaccine stocks was performed.

On March 6, 2019, CDC notified the World Health Organization (WHO) of a possible Public Health Emergency of International Concern (PHEIC) under the International Health Regulations. In order to notify an event as a PHEIC, CDC must assess the public health impact to be serious. CDC assesses these importations to be serious because rabies has a high potential to cause an epidemic, there is indication of treatment failure, and the importations represent a significant public health risk even if very few human cases are identified.

The worst-case outcomes for an importation of a rabid dog would include (1) transmission of CRVV to an unaware person because rabies is usually fatal once persons become symptomatic or (2) unrecognized spread to other wildlife species with subsequent, and possibly sustained, transmission in the United States.

The cost of re-introduction of CRVV could be especially high if CRVV spreads to other species of U.S. wildlife. A reintroduction of CRVV into the United States would require costly efforts over a number of years to eliminate the virus. A previous campaign to eliminate domestic dog-coyote rabies virus variant jointly with gray fox (Texas fox) rabies virus variant in Texas over the period from 1995 through 2003 cost an undiscounted $34 million [5] [6] or $52 million in 2019 U.S. dollars. The costs to contain any reintroduction of CRVV would depend on how much time passed before the reintroduction was realized, the wildlife species in which CRVV was transmitted, and the geographic area over which reintroduction occurs. The above estimate is limited to the cost of rabies vaccination programs for targeted wildlife and does not include the costs to administer post-exposure prophylaxis to any persons exposed after the reintroduction has been identified.

Even under the best-case scenario in which a dog with CRVV is imported, but quickly identified, costs would be incurred for the public health response to provide post exposure prophylaxis for exposed persons and monitor exposed animals. The HHS/CDC Poxvirus and Rabies Branch estimates that each importation could require an intensive public health response comprising of 800 staff-hours.[7]

In addition, HHS/CDC estimates that each rabid dog importation event would result in approximately 15.5 human exposures.[8] [9] [10] [11] Each human exposure would be expected to require post-exposure prophylaxis to ensure that people do not develop rabies, which is usually fatal once symptoms appear. Rabies post-exposure prophylaxis includes one dose of rabies immune globulin plus four doses of rabies vaccine. The total cost including office visits was estimated at about $8,500 per exposed individual, although actual costs would depend on where a person receives post exposure prophylaxis.

An imported dog with CRVV may also expose other animals. HHS/CDC's Poxvirus and Rabies Branch estimates that approximately 29.6 animals [11] [12] [13] [14] would be exposed for each imported dog with CRVV and that the average cost per exposed animal would be $1,000.[15]

The total cost per event (Table 1) including public health response, human exposures, and animal exposures is estimated at slightly less than $214,000. Lower bound and upper bound estimates were calculated by multiplying by 80% and 120% since the public health response time, persons and animals exposed may vary considerably for any given importation of a dog with CRVV. The estimated range in costs is from $171,000 to $257,000.

[5] TJ Sidwa et al. (2005) Evaluation of oral rabies vaccination programs for control of rabies epizootics in coyotes and gray foxes: 1995–2003. Journal of the American Veterinary Medicine Association; 227(5):785–92.

[6] R.T. Sterner et al. (2009) Tactics and Economics of Wildlife Oral Rabies Vaccination, Canada and the United States. Emerging Infectious Diseases; 15(8):

[7] Personal communication: Ryan M Wallace and Jesse D Blanton U.S. Centers for Disease Control and Prevention, Poxvirus and Rabies Branch; February 23, 2018.

[8] Sinclair JR, Wallace RM, Gruszynski K, Freeman MB, Campbell C, et al. Rabies in a Dog Imported with Falsified Rabies Vaccination Certificate—Virgiania, 2015. MMWR Morb Mort Wkly Rep 2015; 64 (49): 1359–62.

[9] Castrodale L, Walker V, Baldwin J, Hofmann J, Hanlon C. Rabies in a puppy imported from India to the USA, March 2007. Zoonoses Public Health 2008;55:427–30.

[10] CDC. Rabies in a Dog Imported from Iraq—New Jersey, June 2008. MMWR Mob Mort Wkly Rep 2008; 57(39):1076–1078.

[11] CDC. An Imported Case of Rabies in an Immunized Dog. MMWR Morb Mort Wkly Rep 1987; 36(7): 94–96.

[11] Sinclair JR, Wallace RM, Gruszynski K, Freeman MB, Campbell C, et al. Rabies in a Dog Imported with Falsified Rabies Vaccination Certificate—Virgiania, 2015. MMWR Morb Mort Wkly Rep 2015; 64 (49): 1359–62.

[12] Castrodale L, Walker V, Baldwin J, Hofmann J, Hanlon C. Rabies in a puppy imported from India to the USA, March 2007. Zoonoses Public Health 2008;55:427–30.

[13] CDC. Rabies in a Dog Imported from Iraq—New Jersey, June 2008. MMWR Mob Mort Wkly Rep 2008; 57(39):1076–1078.

[14] CDC. An Imported Case of Rabies in an Immunized Dog. MMWR Morb Mort Wkly Rep 1987; 36(7): 94–96.

[15] Personal communication: Ryan M Wallace and Jesse D Blanton U.S. Centers for Disease Control and Prevention, Poxvirus and Rabies Branch; February 23, 2018.

TABLE 1—ESTIMATED PUBLIC HEALTH RESPONSE, HUMAN POST-EXPOSURE PROPHYLAXIS AND ANIMAL EXPOSURE COSTS ESTIMATED PER IMPORTATION OF A DOG WITH CANINE RABIES VIRUS VARIANT (CRVV), ASSUMING NO TRANSMISSION TO U.S. HUMANS OR ANIMALS

Public health response cost					
Number of hours per importation (A) [a]	Public health department employee hourly cost (B) [b]	Overhead cost estimate (C)	Cost per importation (A × B × (100% + C))	Lower bound (−20%)	Upper bound (+20%)
800	$32.21	100% of wage rate.	$51,536	$41,229	$61,843
Human post-exposure prophylaxis cost					
Number of exposed people (D) [a]	Average cost for post-exposure prophylaxis per person (E) [c]		Cost per importation (D × E)	Lower bound (−20%)	Upper bound (+20%)
15.6	$8,508		$132,727	$106,182	$159,272
Number of exposed animals per importation (F) [a]	Average cost per exposed animal (G) [a]		Cost per importation (F × G)	Lower bound (−20%)	Upper bound (+20%)
29.6	$1,000		$29,570	$23,656	$35,484
Total cost per importation					
Total cost per importation event			$213,833	$171,066	$256,599

[a] Personal communication: Ryan M. Wallace and Jesse D. Blanton U.S. Centers for Disease Control and Prevention, Poxvirus and Rabies Branch; February 23, 2018.

[b] Bureau of Labor Statistics, May 2017 National Occupational Employment and Wage Estimates United States, Occupation codes 29–1131, 19–1041, 29–1141, 29–2061, 43–0000.

[c] Rabies immune globulin and vaccine Red Book Online [database online]. Greenwood Village, CO: Truven Health Analytics. *http://www.micromedexsolutions.com/.* Accessed June 25, 2018.

Centers for Medicare and Medicaid Services. 2017 Medicare Physician Fee Schedule. *http://www.cms.gov/apps/physician-fee-schedule/overview.aspx.* Accessed June 25, 2018.

P. Dhankhar, SA. Vaidya, DB Fishbien, MI Meltzer (2008) Cost effectiveness of rabies post-exposure prophylaxis in the United States. Vaccine 26: 4251–4255.

S.M. Kreindel, M. McGuill, M. Meltzer, C. Rupprecht, A. DeMaria Jr. (1998) The cost of rabies postexposure prophylaxis: one state's experience. Public Health Rep 113:247–51.

IV. Authority and Operations

Under 42 CFR 71.51, HHS/CDC requires each imported dog from a country with a high risk of CRVV to appear healthy and be accompanied by a valid rabies vaccination certificate indicating that the animal has been vaccinated against rabies prior to entry into the United States. The exception to this requirement is for dogs imported for scientific research purposes when rabies vaccination would interfere with the purpose of the research. Additionally, under 42 CFR 71.63, the CDC Director may temporarily suspend the entry of animals, articles, or things from designated foreign countries and places into the United States when the Director has determined there exists in a foreign country a communicable disease that would threaten the public health of the United States and the entry of imports from that country would increase the risk that the communicable disease may be introduced. Under 42 CFR 71.51(e), the CDC Director may also exclude dogs coming into the United States from areas determined to have high rates of rabies.

CDC has identified countries and political units that are considered high risk for importing CRVV into the United States. Egypt has been identified as one such country.[12] Therefore, under 42 CFR 71.51, any dogs coming from Egypt must be accompanied by valid rabies vaccine certificates to enter the United States. All of the dogs in the January 29, 2019 shipment entered with what appeared to be valid rabies certificates, suggesting a systemic failure of the rabies vaccination system in Egypt.

In light of these repeated rabid dog importations, CDC has determined that until appropriate veterinary controls are in place in Egypt, a rabies vaccination certificate is not sufficient to protect U.S. public health against rabid dogs being imported from Egypt. For this reason, under 42 CFR 71.63 and 42 CFR 71.51(e), CDC is exercising its authority to temporarily suspend entry of imported dogs from Egypt, including dogs from Egypt that are imported by way of third-party countries if the dogs have been present in the third-party country for less than six months. Six months is the upper range of the incubation period for rabies in dogs. Thus, vaccinated dogs that have been present in a third-party country for more than six months may be safely imported into the United States, assuming all other CDC requirements are met. CDC will continue this suspension until appropriate veterinary safeguards to prevent the importation of canine rabies from Egypt have been established. CDC will also review this suspension on a periodic basis to ensure that it does not remain in place longer than is necessary to protect U.S. public health.

[12] Factors that warrant placing a country on the list include documented presence of CRVV (publications or reports), inadequate or a lack of evidence of active control measures (mass dog vaccination), and consultation with regional rabies experts (typically OIE or WHO/PAHO regional representatives).

V. Advance Written Approval

The provisions of this notice do not apply if advance written approval from the CDC has been obtained to import a

dog from Egypt, including a dog from Egypt that is being imported from a third-party country. Such approvals will be granted on a limited and case-by-case basis and at CDC's discretion.

Individuals seeking to import a dog from Egypt must submit the Application for a Permit to Import a Dog Inadequately Immunized Against Rabies, which is currently approved under OMB Control Number 0920–0134 Foreign Quarantine Regulations (exp. 03/31/2022).

To request the advance written approval of the CDC, you must send an email to the Director, Division of Global Migration and Quarantine, at *cdcanimalimports@cdc.gov,* requesting an application. Once you receive instructions and the permit application, your request must be submitted at least 10 business days before the date on which you intend the dog to enter the United States. A request cannot be made at the port of entry upon arrival into the United States. As required by the permit application, your request must present sufficient, reliable evidence conclusively demonstrating that the dog you wish to import is immune from rabies. Such evidence includes a valid rabies vaccination certificate that was issued in the United States or official government documents demonstrating the reliability of the vaccine, vaccine provider, and conditions under which the vaccine was stored. The evidence you present must also demonstrate the authenticity of the documents relied upon. Your written request must further explain how you intend to establish, for example, through identifying markers, microchip, or tattoo, that the dog being imported is the same dog identified in the official government documents you provided to the CDC. If the official government documents are not written in English, then they must be accompanied by English language translations of the official government documents, the authenticity of which has been attested to by a person licensed by the government to perform acts in legal affairs.

CDC will respond to your request in writing and may impose additional conditions in granting the approval. You must present CDC's written response and approval upon entry into the United States. If your request for advance approval is denied, CDC's written denial will constitute final agency action.

VI. Terms of This Notice

Pursuant to 42 CFR 71.63 and 42 CFR 71.51(e), HHS/CDC hereby suspends, until further notice, the importation of any dog from Egypt, including dogs from Egypt that are imported from third-party countries if the dogs have been present in those countries for less than six months. This notice will become effective on May 10, 2019, and will be remain in place subject to periodic review by the CDC until appropriate safeguards to prevent importation of CRVV from Egypt have been established.

Dated: May 6, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–09654 Filed 5–9–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; State Temporary Assistance for Needy Families Case Studies (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) is proposing a data collection activity as part of the State Temporary Assistance for Needy Families (TANF) Case Studies project. This study seeks to document innovative employment and training programs for low-income individuals including TANF recipients and examine the ways the programs provide or link families to wraparound services. Over a three-year period, the study will conduct up to 12 comprehensive qualitative case studies and up to 20 profiles of innovative programs to showcase promising approaches.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also 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, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The State TANF Case Studies project will involve several phases including: (1) Identifying innovative programs through a scan of the field and engagement with stakeholders; (2) visiting up to 12 selected programs to collect detailed information and produce comprehensive case studies of these programs to enhance policymakers' and other stakeholders' understanding of promising programs helping low-income individuals to succeed in the labor force; and (3) gathering information through telephone interviews to produce up to 20 shorter case studies. The proposed information collection activities are: (1) Semi-structured interviews with program and partner administrators and frontline staff; (2) in-depth interviews with participants to better inform and enhance understanding of client experiences and perspectives; (3) a guided case review with frontline staff to capture information about client characteristics as well as intensity, frequency, duration, and sequencing of services; and (4) an observation of program services, such as case management sessions, intakes and referrals, services delivered in a classroom setting, and work sites. The study will take place over a three year period.

Respondents: Respondents include program administrators, frontline program staff, and program participants. Program administrators include staff who administer and supervise the case study program under review; TANF and employment and training programs; child care and other wraparound supports; and other workforce programs and partners such as community colleges, adult basic education providers, and employers; and state decision makers, as appropriate. Frontline program staff include intake workers, case managers, job developers, and other direct service providers who work at TANF agencies and American Job Centers, employment and training providers such as community colleges, and providers of wraparound supports, such as child care subsidy frontline staff. TANF and other low-income program participants will also be respondents. All participants will be able to opt out of participating in the data collection activities.

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
Semi-structured program staff interview guide	200	67	1	1	67
In-depth participant interview guide	24	8	1	1.5	12
Case review guide	24	8	2	.75	12

Estimated Total Annual Burden Hours: 91.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 413, Pub. L. 115–31.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–09658 Filed 5–9–19; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1798]

Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' This guidance represents FDA's current thinking on the conduct of in vivo absorption trials for topically applied active ingredients that are under consideration for inclusion in an over-the-counter (OTC) monograph.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–1798 for ''Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the

heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993–0002, 240–402–4246.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' This guidance represents FDA's current thinking on the conduct of in vivo absorption trials for topically applied active ingredients that are under consideration for inclusion in an OTC monograph. A maximal usage trial (MUsT) is a standard approach to assessing the in vivo bioavailability of topical drug products. The methodology described in this guidance adapts MUsT principles for active ingredients being considered for inclusion in an OTC monograph. Because information from a MUsT can help identify the potential for systemic exposure to a topically applied active ingredient, such information can help inform an FDA determination of whether additional safety data are needed to support a finding that a topical OTC drug containing that active ingredient is generally recognized as safe and effective for its intended use.

This guidance was written, in part, in response to comments submitted to Docket No. FDA–2015–D–4021 for the draft guidance entitled ''Over-the-Counter Sunscreens: Safety and Effectiveness Data'' (80 FR 72975, November 23, 2015) and the final guidance that replaced it, entitled ''Nonprescription Sunscreen Drug Products—Safety and Effectiveness Data,'' (81 FR 84594, November 23, 2016), requesting that FDA provide further guidance and details on the MUsT recommended in that document. FDA has also recommended a MUsT to address data gaps regarding active ingredients under consideration for inclusion in the OTC monograph for topical antimicrobial drug products, and in the OTC sunscreen monograph rulemaking (see proposed rules ''Safety and Effectiveness of Consumer Antiseptics, Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record'' (81 FR 42912, June 30, 2016) and ''Sunscreen Drug Products for Over-the-Counter Human Use'' (84 FR 6204, February 26, 2019)). This guidance provides additional information on the study elements, data analysis, and considerations when designing a MUsT for a topically applied active ingredient being considered for inclusion in an OTC monograph.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-the-Counter Monograph: Study Elements and Considerations.'' 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. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09692 Filed 5–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2165]

Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' The purpose of this guidance is to assist sponsors in evaluating reproductive toxicity (mainly related to embryo-fetal development (EFD)) for anticancer pharmaceuticals and to provide recommendations to applicants for pharmaceutical labeling on duration of contraception following cessation of therapy to minimize potential risk to a developing embryo or fetus. The guidance also clarifies FDA's current thinking on when nonclinical studies for reproductive toxicology assessment may not be needed (*e.g.,* for pharmaceuticals intended for use in postmenopausal women only). The intended outcome of this guidance is to facilitate the development of oncology pharmaceuticals while avoiding unnecessary use of animals, in accordance with the 3R (reduce, refine, replace) principles, and to provide a consistent approach to labeling recommendations for the duration of contraception after completion of therapy. This guidance finalizes the guidance of the same name issued September 29, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–2165 for ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993–0002, 301–796–7550; or Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993–0002, 301–796–7550.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' This guidance represents FDA's current approach to assessing potential risk to a developing embryo or fetus associated with the use of anticancer pharmaceuticals in male and female patients. The term oncology pharmaceutical in this guidance refers to small molecules, biotechnology-derived products, and related compounds such as conjugated products. This guidance describes: (1) How to evaluate EFD toxicity for various types of pharmaceuticals, such as for genotoxic, biological, conjugated, and combination products; (2) whether reproductive toxicity assessment is warranted for specific patient populations, such as pharmaceuticals being developed for use in male patients only or in postmenopausal women only; and (3) recommendations for the duration of contraception after completion of therapy to minimize risk to a developing embryo or fetus.

Although, current regulatory guidances exist regarding the need to assess the EFD toxicity potential of pharmaceuticals and the overall design of the studies, this guidance provides additional recommendations for evaluation of EFD toxicity for specific types of pharmaceuticals and for specific populations, which are not covered under other guidances. This guidance also expands on the weight of evidence approaches that could be utilized to substitute for dedicated EFD toxicology studies and hence facilitate the development of oncology pharmaceuticals while avoiding unnecessary use of animals, in accordance with the 3R principles. Moreover, this guidance provides labeling recommendations on the duration of contraception after completion of therapy, not previously addressed in other guidance documents. This guidance finalizes the guidance of the same name issued on September 29, 2017 (82 FR 45593).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of

information in 21 CFR 201.56 and 201.57 and the final rule ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling'' have been approved under OMB control numbers 0910–0572 and 0910–0624.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: May 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09691 Filed 5–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2478]

Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration is announcing the availability of a final guidance entitled ''Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.'' The final guidance document notifies blood establishments that collect blood and blood components that we have determined babesiosis to be a relevant transfusion-transmitted infection (RTTI) and provides recommendations for donor screening, donation testing, donor deferral, and product management to reduce the risk of transfusion-transmitted babesiosis (TTB). The recommendations contained in the guidance apply to the collection of blood and blood components, except Source Plasma. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2018–D–2478 for ''Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jenifer Stach, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.'' The guidance document notifies blood establishments that collect blood and blood components that we have determined babesiosis to be an RTTI under 21 CFR 630.3(h)(2) and provides recommendations for donor screening, donation testing, donor deferral, and product management to reduce the risk of TTB. The recommendations contained in the guidance document applies to the collection of blood and blood components, except Source Plasma.

In the **Federal Register** of July 27, 2018 (83 FR 35657), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated July 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for reducing the risk of transfusion-transmitted babesiosis. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338, and the collections of information in 21 CFR part 606, 21 CFR 610.40(h), and 21 CFR 630.40 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09676 Filed 5–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5974]

Determining Whether To Submit an Abbreviated New Drug Application or a 505(b)(2) Application; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' This guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the Federal Food, Drug, and Cosmetic Act (FD&C Act) is appropriate for the submission of a marketing application to FDA. The guidance announced in this notice finalizes the draft guidance with the same name dated October 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2017–D–5974 for ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80

FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1670, Silver Spring, MD 20993, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' This guidance is intended to serve as a foundational guidance to assist applicants in determining which one of the abbreviated approval pathways under the FD&C Act is appropriate for the submission of a marketing application to FDA. This guidance highlights criteria for submitting applications under the abbreviated approval pathways described in section 505(j) and 505(b)(2) of the FD&C Act (21 U.S.C. 355(j) and 21 U.S.C. 355(b)(2), respectively), identifies considerations to help potential applicants determine whether an application would be more appropriately submitted under section 505(j) or pursuant to section 505(b)(2) of the FD&C Act, and provides direction to potential applicants on requesting assistance from FDA in making this determination.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) added section 505(b)(2) and 505(j) of the FD&C Act, which describe abbreviated approval pathways for drug products regulated by the Agency under the FD&C Act. The Hatch-Waxman Amendments reflect Congress's efforts to balance the need to ''make available more low cost generic drugs by establishing a generic drug approval procedure'' with new incentives for drug development in the form of exclusivities and patent term extensions. With the passage of the Hatch-Waxman Amendments, the FD&C Act describes different routes for obtaining approval of two broad categories of drug applications: New drug applications (NDAs) and abbreviated new drug applications (ANDAs).

This guidance focuses on those applications that can be submitted as ANDAs under section 505(j) of the FD&C Act, petitioned ANDAs under section 505(j)(2)(C) of the FD&C Act, or NDAs pursuant to section 505(b)(2) of the FD&C Act. This guidance does not discuss stand-alone NDAs.

In the **Federal Register** of October 13, 2017 (82 FR 47749), FDA announced the availability of the draft guidance of the same title dated October 2017. FDA received four comments on the draft guidance and those comments were considered as the guidance was finalized. We note that we received comments requesting clarification on the process for obtaining therapeutic equivalence evaluations. We will address therapeutic equivalence in a forthcoming guidance document (see ''Guidance Agenda: New and Draft Guidances CDER Plans to Publish During Calendar Year 2019''). The final guidance contains minor clarifications to the draft guidance. The guidance announced in this notice finalizes the draft guidance dated October 2017.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Determining Whether to Submit an ANDA or a 505(b)(2) Application.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.94 have been approved under OMB control number 0910–0001. The collection of information for controlled correspondence and pre-ANDA meeting requests has been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09662 Filed 5–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Chart Abstraction of Ryan White HIV/AIDS Program Recipient Data, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 9, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA

Information Collection Clearance Officer, at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Chart Abstraction of Ryan White HIV/AIDS Program Data, OMB No. 0906–xxxx–New.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately three-quarters of RWHAP clients are racial and ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

HRSA is required to assess the quality of care provided by RWHAP grant recipients. HHS guidelines (*e.g.,* Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV; Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents; and Sexually Transmitted Diseases Treatment Guidelines, 2015) and U.S. Preventative Services Task Force (USPSTF) guidelines serve as the basis for assessing the quality of care within the RWHAP. The purpose of the *Chart Abstraction of RWHAP Data* study is to assess the extent to which the care provided with funding from the RWHAP is meeting the HHS and USPSTF guidelines. The study will collect data from RWHAP service providers via a provider screening phone interview, a provider pre-site visit interview, and medical records data abstraction. The data will reflect the full range of HIV outpatient ambulatory health services, primary care, and screening and treatment for hepatitis, sexually transmitted infections (STIs), and opioid use disorder provided through the RWHAP and allow HRSA to assess the extent to which care provided with funding through the RWHAP meets the HHS and USPSTF guidelines.

Need and Proposed Use of the Information: National RWHAP client-level data is collected through the RWHAP Client Level Data Reporting System. The RWHAP Client Level Data Reporting System dataset (OMB control number 0915–0323) is HRSA's primary source of annual, client-level data collected from its nearly 2,000 funded grant recipients/service providers and the data have been used to assess the numbers and types of clients receiving services and limited HIV outcomes. However, the RWHAP Client Level Data Reporting System dataset does not include relevant data in order to fully assess the extent to which the care provided with funding from the RWHAP is meeting the HHS and USPSTF guidelines. This proposed new ICR will provide the full range of HIV outpatient ambulatory health services, primary care, and screening and treatment for hepatitis, STIs, and opioid use disorder data and allow HRSA to assess the extent to which care provided with funding through the RWHAP meets the HHS and USPSTF guidelines.

Likely Respondents: HRSA RWHAP Part A, Part B, Part C, and Part D service providers funded to deliver outpatient ambulatory health services to eligible clients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Provider Site screening interview	100	1	100	.5	50
Provider Pre-Site Visit Interview	50	1	50	1	50
Medical Record Data Abstraction	50	1	50	2	100
Total	200		200		200

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–09666 Filed 5–9–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2019 Schedule

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: 2019 public meeting dates of the Health Information Technology Advisory Committee.

SUMMARY: The Health Information Technology Advisory Committee

(HITAC) was established in accordance with section 4003(e) of the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the National Coordinator for Health Information Technology (National Coordinator). The HITAC will hold public meetings throughout 2019. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Lauren Richie, Designated Federal Officer, at *Lauren.Richie@hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition

The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;
- 3 members are appointed by the HHS Secretary
  - 1 of whom shall be appointed to represent the Department of Health and Human Services and
  - 1 of whom shall be a public health official;
- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives; and
- Other members are appointed by the Comptroller General of the United States.

Members will serve for one-, two-, or three-year terms. All members may be reappointed for subsequent three-year terms. Each member is limited to two three-year terms, not to exceed six years of service. After establishment, members shall be appointed for a three-year term. Members serve without pay, but will be provided per-diem and travel costs for committee services.

Recommendations

The HITAC recommendations to the National Coordinator are publicly available at *https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it.*

Public Meetings

The schedule of meetings to be held in 2019 is as follows:

- February 20, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- March 19–20, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time each day at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- April 10, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- April 25, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- May 13, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- May 22, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- June 13, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- June 19, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- July 11, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- September 17, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time at the Key Bridge Marriott Hotel, 1401 Lee Highway, Arlington, Virginia 22209
- October 16, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- November 13, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)

All meetings are open to the public. Additional meetings may be scheduled as needed. For web conference instructions and the most up-to-date information, please visit the HITAC calendar on the ONC website, *http://www.healthit.gov/FACAS/calendar.*

Contact Person for Meetings: Lauren Richie, *lauren.richie@hhs.gov*. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Please email Lauren Richie for the most current information about meetings.

Agenda: As outlined in the 21st Century Cures Act, the HITAC will develop and submit recommendations to the National Coordinator on the topics of interoperability, privacy and security, and patient access. In addition, the committee will also address any administrative matters and hear periodic reports from ONC. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its website prior to the meeting, the material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's website after the meeting, at *http://www.healthit.gov/hitac.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person prior to the meeting date. An oral public comment period will be scheduled at each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ONC will take written comments after the meeting.

Persons attending ONC's HITAC meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its HITAC meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lauren Richie at least seven (7) days in advance of the meeting.

Notice of these meetings are given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: May 2, 2019.

Lauren Richie,

Office of Policy, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2019–09612 Filed 5–9–19; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Radiation Therapeutics and Biology Study Section.

Date: June 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Development—2 Study Section.

Date: June 10–11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Torrance Marriott Redondo Beach, 3635 Fashion Way, Torrance, CA 90503.

Contact Person: Rass M. Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: June 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037.

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301–402–4411, *tianbi@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Bioengineering, Technology and Surgical Sciences Study Section.

Date: June 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Torrance Marriott Redondo Beach, 3635 Fashion Way, Torrance, CA 90503.

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Mechanisms of Sensory, Perceptual, and Cognitive Processes Study Section.

Date: June 11–12, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Immune Responses and Vaccines to Non-HIV Microbial Infections.

Date: June 11, 2019.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Andrea Keane-Myers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, Bethesda, MD 20892, 301–435–1221, *andrea.keane-myers@nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Cardiovascular Differentiation and Development Study Section.

Date: June 11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20817–7814, 301–435–0904, *sara.ahlgren@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Analgesic Properties of Minor Cannabinoids and Terpenes.

Date: June 11, 2019.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: June 12–13, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular Aspects of Diabetes and Obesity Study Section.

Date: June 12–13, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.

Contact Person: Antonello Pileggi, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, Bethesda, MD 20892–7892, (301) 402–6297, *pileggia@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

Date: June 12, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC 7850, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cellular Aspects of Diabetes and Obesity.

Date: June 12, 2019.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102 (Telephone Conference Call).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182 MSC 7892, Bethesda, MD 20892, 301 435–2514, *riverase@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 6, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09617 Filed 5–9–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Introduction to Cancer Research Careers (ICRC) Application (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Agustina Boswell, Program Coordinator, Office of Workforce Planning and Development, National Cancer Institute, 9609 Medical Center Drive, Room 2E–134, Rockville, Maryland 20892 or call non-toll-free number (240) 276–5162 or Email your request, including your address to: *boswellam@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The National Cancer Institute's Introduction to Cancer Research Careers (ICRC) Application (NCI), 0925–XXXX, Exp., Date XX/XXXX, NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute's (NCI) ICRC fellowship program supports NCI's goal of training cancer researchers for the 21st century. Applying to the ICRC program through the ICRC website application is required in order for undergraduates, postbaccalaureate, graduate student candidates to be considered for entry into the program. The purpose of the ICRC Application is to assure that candidates for the ICRC program meet basic eligibility requirements; to assess their potential as future scientists; to determine where mutual research interests exist; and to make decisions regarding which applicants will be proposed and approved for fellowship awards. The information is for internal use to make decisions about prospective fellows and students that could benefit from the ICRC program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 240 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Application	Individuals	120	1	60/60	120
Reference Letter	Individuals	240	1	30/60	120
Total		360	360		240

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2019–09615 Filed 5–9–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Community Influences on Health Behavior Study Section.

Date: June 4–5, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn by Marriott Alexandria, 1456 Duke Street, Alexandria, VA 22314.

Contact Person: Tasmeen Weik, DRPH, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, 301–827–6480, *weikts@mail.nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Hypertension and Microcirculation Study Section.

Date: June 4–5, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Hypertension and Microcirculation.
Date: June 4, 2019.
Time: 10:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Residence Inn Bethesda, 7355 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *Katherine_Malinda@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Clinical Studies of Mental Illness.
Date: June 4, 2019.
Time: 1:00 p.m. to 1:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.
Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–500–5829, *sechu@csr.nih.gov*.

Name of Committee: Vascular and Hematology Integrated Review Group; Vascular Cell and Molecular Biology Study Section.
Date: June 6–7, 2019.
Time: 7:30 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.
Contact Person: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Chronic Dysfunction and Integrative Neurodegeneration Study Section.
Date: June 6–7, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.
Contact Person: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 408–9866, *manospa@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Developmental Brain Disorders Study Section.
Date: June 6–7, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Renaissance, Washington, DC Hotel, 999 Ninth Street NW, Washington, DC 20001.
Contact Person: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–408–9866, *manospa@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.
Date: June 6–7, 2019.
Time: 8:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037.
Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, *cinquej@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Skeletal Biology Structure and Regeneration.
Date: June 6, 2019.
Time: 11:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Residence Inn Pentagon City, 550 Army Navy Drive, Arlington, VA 22202.
Contact Person: Aruna K. Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–435–6809, *beheraak@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 6, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09619 Filed 5–9–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Behavioral Genetics and Epidemiology Study Section.
Date: June 4–5, 2019.
Time: 8:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Grand Seattle, 1400 Sixth Avenue, Seattle, WA 98101.
Contact Person: Gianina Ramona Dumitrescu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4193–C, Bethesda, MD 28092, 301–827–0696, *dumitrescurg@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies B Study Section.
Date: June 6–7, 2019.
Time: 9:00 a.m. to 1:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites Hotel, 4300 Military Road, Washington DC, DC 20015.
Contact Person: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–2309, *fothergillke@mail.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Development—1 Study Section.
Date: June 6–7, 2019.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Thomas Beres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7840, Bethesda, MD 20892, 301–435–1175, *berestm@mail.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.
Date: June 10–11, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.
Contact Person: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301–435–1718, *sizemoren@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.
Date: June 13–14, 2019.
Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Virginian Suites, 1500 Arlington Boulevard, Arlington, VA 22209.

Contact Person: Baljit S. Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@mail.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Drug Discovery and Mechanisms of Antimicrobial Resistance Study Section.

Date: June 13–14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

Contact Person: Guangyong Ji, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, MSC 7808, Bethesda, MD 20892, 301–435–1146, *jig@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Progression and Metastasis Study Section.

Date: June 13–14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718, *jakobir@mail.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Clinical Research and Field Studies of Infectious Diseases Study Section.

Date: June 13–14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Soheyla Saadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, *saadisoh@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: June 13–14, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5205, MSC7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

Date: June 13, 2019.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Geoffrey G Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neural Oxidative Metabolism and Death Study Section.

Date: June 13–14, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 6, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09621 Filed 5–9–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel for Review of Conference Grant (R13) applications.

Date: June 12, 2019.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, Suite 525, 7201 Wisconsin Avenue MSC 9205, Bethesda, MD 20892 (Telephone Assisted Meeting).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20906, (301) 451–2432, *ismonddr@mail.nih.gov.*

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel for RCMI Conference Grant applications.

Date: June 18, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, Suite 525, 7201 Wisconsin Avenue MSC 9205, Bethesda, MD 20892.

Contact Person: Maryline Laude-Sharp, Ph.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20906, (301) 451–2432, *ismonddr@mail.nih.gov.*

Dated: May 6, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09616 Filed 5–9–19; 8:45 am]

BILLING CODE 4140–01–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 owned by an agency of the U.S. Government and 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: Chris Kornak at 240–627–3705 or

Chris.Kornak@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Continuous Cell Lines Persistently Expressing High Levels of Native HIV–1 Envelope Trimers on Their Surface Membrane

Description of Technology: Transduced human cell lines expressing high levels of native HIV–1 Envelope on their surface membrane, in the unmodified or interdomain stabilized form. These cell lines provide a stable source of native HIV–1 envelope for multiple uses, including the high-efficiency production of virus-like particles (VLPs) for use as vaccines, testing new inhibitors or neutralizing antibodies, or identifying/capturing B cells that produce broadly neutralizing antibodies from infected/vaccinated humans or animals.

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:

- High-efficiency production of virus-like particles (VLPs).
- A means to test new inhibitors or neutralizing antibodies targeting HIV–1 envelope trimers.
- Probe for identifying/capturing B cells that produce broadly neutralizing antibodies.

Competitive Advantages:

- The interdomain-stabilized form does not bind CD4 and is locked in the native prefusion form.

Development Stage:

- Research Use.

Inventors: Paolo Lusso (NIAID), Peng Zhang (NIAID).

Publications: Zhang, Peng, et al. ''Interdomain stabilization impairs CD4 binding and improves immunogenicity of the HIV–1 envelope trimer.'' Cell host & microbe 23.6 (2018): 832–844.

Licensing Contact: To license this technology please reference E–185–2018–0, and contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.*

Dated: April 30, 2019.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2019–09618 Filed 5–9–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0264]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0105

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0105, Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District and the Illinois Waterway, Ninth Coast Guard District; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 9, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2019–0264] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2019–0264], and must be received by July 9, 2019.

Submitting Comments

We encourage you to submit comments through the Federal

eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District and the Illinois Waterway, Ninth Coast Guard District.

OMB Control Number: 1625–0105.

Summary: The Coast Guard requires position and intended movement reporting, and fleeting operations reporting, from barges carrying certain dangerous cargoes (CDCs) in the inland rivers within the Eighth and Ninth Coast Guard Districts. The reporting requirements are found in 33 CFR 165.830 and 165.921.

Need: This information is used to ensure port safety and security and to ensure the uninterrupted flow of commerce.

Forms: None.

Respondents: Owners, agents, masters, towing vessel operators, or persons-in-charge of barges loaded with CDCs or having CDC residue operating on the inland rivers located within the Eighth and Ninth Coast Guard Districts.

Frequency: On occasion.

Hour Burden Estimate: The estimated annual burden remains 4 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: May 6, 2019.

James D. Roppel,

U.S. Coast Guard, Chief, Office of Information Management.

[FR Doc. 2019–09646 Filed 5–9–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0108]

Agency Information Collection Activities: Canadian Border Boat Landing Permit

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and must be submitted (no later than June 10, 2019) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (84 FR 4835) on February 19, 2019, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Canadian Border Boat Landing Permit.

OMB Number: 1651–0108.

Form Number: CBP Form I–68.

Current Actions: This submission is being made to extend the expiration date with a decrease to the burden hours. There is no change to the information collected.

Type of Review: Extension (With Change).

Affected Public: Individuals or Households.

Abstract: The Canadian Border Boat Landing Permit, U.S. Customs and Border Protection (CBP) Form I–68, allows select individuals entering the United States along the northern border by small [1] pleasure boats to report their arrival and make entry without having to travel to a designated port of entry for an inspection by a CBP officer. United States citizens, Lawful Permanent Residents of the United States, Canadian citizens, and Landed Residents of Canada who are nationals of the Visa Waiver Program countries listed in 8

[1] Weighing less than five net tons.

CFR 217.2(a) are eligible to apply for the permit.

The information collected on CBP Form I–68 is provided for by 8 CFR 235.1(g) and Section 235 of Immigration and Nationality Act. CBP Form I–68 is accessible at *http://www.cbp.gov/newsroom/publications/forms?title=68&=Apply.*

CBP has developed a smart phone application known as ROAM that will in certain circumstances allow travelers participating in the I–68 program to report their arrival in the United States through the ROAM application, instead of by telephone. The ROAM app, implementing the I–68 program, will allow CBP officers to remotely conduct traveler interviews with a phone's video chat capability, and replace other technologies used for remote inspections that are obsolete or inefficient.

CBP Form I–68 Paper Version

Estimated Number of Respondents: 18,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Responses: 18,000.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 2,988.

ROAM App

Estimated Number of Respondents: 50,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 50,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 4,150.

Dated: May 6, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–09613 Filed 5–9–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2641–19; DHS Docket No. USCIS–2018–0005]

RIN 1615–ZB78

Continuation of Documentation for Beneficiaries of Temporary Protected Status Designations for Nepal and Honduras

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces actions to ensure its compliance with the order of the U.S. District Court for the Northern District of California to stay proceedings in *Bhattarai* v. *Nielsen,* No. 19–cv–00731 (N.D. Cal. Mar. 12, 2019) (''order to stay proceedings''). The claims raised in *Bhattarai* v. *Nielsen* are similar to, and will be informed by the resolution of, the claims being litigated before the Ninth Circuit Court of Appeals in *Ramos* v. *Nielsen,* No. 18–16981 (9th Cir. filed Oct. 12, 2018). For that reason, DHS will not implement or enforce the decision to terminate Temporary Protected Status (TPS) for Honduras or Nepal pending the resolution of the *Ramos* v. *Nielsen* appeal, or by other order of the court. Beneficiaries under the TPS designations for Nepal and Honduras will retain their TPS, provided that an individual's TPS status is not withdrawn because of ineligibility.

DHS is further announcing it is automatically extending through March 24, 2020, the validity of TPS-related Employment Authorization Documents (EADs), Forms I–797, Notice of Action (Approval Notice), and Forms I–94 (Arrival/Departure Record) (collectively ''TPS-Related Documentation''), as specified in this Notice, for beneficiaries under the TPS designation for Nepal, provided that the affected TPS beneficiaries remain otherwise individually eligible for TPS. The TPS designation for Honduras remains in effect through January 5, 2020. *See* 83 FR 26074 (June 5, 2018). This Notice also provides information explaining DHS's plans to issue subsequent notices that will describe the steps DHS will take to address the TPS status of beneficiaries under the TPS designations for Honduras and Nepal, if continued compliance with the order to stay proceedings during the pendency of the *Ramos* v. *Nielsen* appeal become necessary.

DATES: The TPS designations of Nepal and Honduras will remain in effect, as required by the order of the U.S. District Court for the Northern District of California adopting the parties' stipulation to stay proceedings in *Bhattarai* v. *Nielsen,* No. 19–cv–00731 (N.D. Cal. Mar. 12, 2019), pending final disposition of the Government's appeal of the preliminary injunction order in *Ramos* v. *Nielsen* enjoining implementation and enforcement of the determinations to terminate the TPS designations for Sudan, Nicaragua, Haiti, and El Salvador, or by other order of the court. DHS will not terminate TPS for Honduras or Nepal pending final disposition of the *Ramos* appeal, including through any additional appellate channels in which relief may be sought, or by other order of the court. Information on the status of the order to stay proceedings and the *Ramos* v. *Nielsen* appeal is available at *http://uscis.gov/tps.*

Further, DHS is automatically extending the validity of TPS-Related Documentation for those beneficiaries under the TPS designation for Nepal, as specified in this Notice. Those documents will remain in effect for nine months through March 24, 2020, provided the individual's TPS is not withdrawn under INA section 244(c)(3) or 8 CFR 244.14 because of ineligibility, and Nepal's TPS designation remains in effect.

In the event the preliminary injunction in *Ramos* v. *Nielsen* is reversed and that reversal becomes final, DHS will allow for a transition period, as described in the ''Possible Future Action'' section of this Notice.

FOR FURTHER INFORMATION CONTACT:

- You may contact Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security, by mail at 20 Massachusetts Avenue NW, Washington, DC 20529–2060; or by phone at 800–375–5283.
- For further information on TPS, please visit the USCIS TPS web page at *http://www.uscis.gov/tps.* You can find specific information about this continuation of the TPS benefits for eligible individuals under the TPS designations for Nepal by selecting the ''Nepal'' page from the menu on the left side of the TPS web page.
- If you have additional questions about Temporary Protected Status, please visit *uscis.gov/tools.* Our online

virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you are unable to find your answers there, you may also call our U.S. Citizenship and Immigration Services (USCIS) Contact Center at 800–375–5283.

• Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

• Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
CFR—Code of Federal Regulations
DHS—U.S. Department of Homeland Security
DOS—U.S. Department of State
EAD—Employment Authorization Document
FNC—Final Nonconfirmation
Form I–94—Arrival/Departure Record
FR—Federal Register
Government—U.S. Government
IJ—Immigration Judge
INA—Immigration and Nationality Act
IER—U.S. Department of Justice Civil Rights Division, Immigrant and Employee Rights Section
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services

Background on Temporary Protected Status (TPS)

• TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the INA, or to eligible persons without nationality who last habitually resided in the designated country.

• During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to obtain EADs so long as they continue to meet the requirements of TPS.

• TPS beneficiaries may also apply for and be granted travel authorization as a matter of discretion.

• The granting of TPS does not result in or lead to lawful permanent resident status.

• To qualify for TPS, beneficiaries must meet the eligibility standards at INA section 244(c)(1)–(2), 8 U.S.C. 1254a(c)(1)–(2).

• When the Secretary terminates a country's TPS designation, beneficiaries return to one of the following:

○ The same immigration status or category that they maintained before TPS, if any (unless that status or category has since expired or been terminated); or

○ Any other lawfully obtained immigration status or category they received while registered for TPS, as long as it is still valid on the date TPS terminates.

Purpose of This Action

Through this **Federal Register** Notice, DHS announces actions to ensure its compliance with the order of the U.S. District Court for the Northern District of California to stay proceedings in *Bhattarai* v. *Nielsen,* No. 19–cv–00731 (N.D. Cal. Mar. 12, 2019). The claims raised in *Bhattarai* v. *Nielsen* are similar to, and will be informed by the resolution, of the claims being litigated before the Ninth Circuit Court of Appeals in *Ramos* v. *Nielsen,* No. 18–16981 (9th Cir. filed Oct. 12, 2018). For that reason, DHS will not implement or enforce the decision to terminate TPS for Honduras or Nepal pending the resolution of the *Ramos* v. *Nielsen* appeal, or by other order of the court. Beneficiaries under the TPS designations for Nepal and Honduras will retain their TPS, provided that an individual's TPS status is not withdrawn under INA section 244(c)(3) because of ineligibility. *See also* 8 CFR 244.14.

DHS is further announcing it is automatically extending through March 24, 2020, the validity of TPS-related EADs, Forms I–797, Notice of Action (Approval Notice), and Forms I–94 (Arrival/Departure Record) (collectively ''TPS-Related Documentation''), as specified in this Notice, for beneficiaries under the TPS designation for Nepal, provided that the affected TPS beneficiaries remain otherwise individually eligible for TPS. *See* INA section 244(c)(3). The validity dates of TPS-Related Documentation for beneficiaries under the TPS designation for Honduras is discussed below. This Notice also provides information explaining DHS's plans to issue subsequent notices that will describe the steps DHS will take to address the TPS status of beneficiaries under the TPS designations for Honduras and Nepal in order to continue its compliance with the order to stay proceedings should such compliance be necessary.

Automatic Extension of EADs

Through this **Federal Register** Notice, DHS automatically extends through March 24, 2020, the validity of EADs with the category codes ''A–12'' or ''C–19'' and one of the expiration dates shown below that have been issued under the TPS designation for Nepal:

06/24/2018
06/24/2019

Additionally, a beneficiary under the TPS designation for Nepal who applied for a new EAD but who has not yet received his or her new EAD is also covered by this automatic extension, provided that the EAD he or she possesses contains one of the expiration dates noted in the chart above. Such individuals may show one of these automatically extended EADs to employers to demonstrate they have employment authorization. Such individuals may also show employers this **Federal Register** Notice, which explains that their EADs have been extended through March 24, 2020. This Notice explains how TPS beneficiaries and their employers may determine which EADs are automatically extended and how this affects the Form I–9, Employment Eligibility Verification, E-Verify, and USCIS Systematic Alien Verification for Entitlements (SAVE) processes.

Automatic Extension of Forms I–94 (Arrival/Departure Record) and Forms I–797 (Notice of Action (Approval Notice))

In addition, through this **Federal Register** Notice, DHS automatically extends through March 24, 2020, the validity periods of the following Forms I–94 and Forms I–797, Notice of Action (Approval Notice) previously issued to eligible beneficiaries granted TPS under the designation for Nepal:

Country	Beginning date of validity:	End date of validity:
Nepal	Dec. 25, 2016 ..... June 25, 2018	June 24, 2018. June 24, 2019.

However, the extension of this validity period applies only if the eligible TPS beneficiary properly filed for TPS re-registration during the most recent DHS-announced registration period for Nepal (May 22, 2018–July 23, 2018), the previous re-registration period (Oct. 26, 2016–Dec. 27, 2016), or has a re-registration application that remains pending. In addition, the extension does not apply if the TPS of any such individual has been finally withdrawn. This Notice does not extend the validity date of any TPS-related Form I–94 or Form I–797, Notice of Action (Approval Notice) issued to a

TPS beneficiary that contains an end date not on the chart above where the individual has failed to file for TPS re-registration, or where his or her re-registration request has been finally denied.

Application Procedures

Current beneficiaries under the TPS designation for Nepal do not need to pay a fee or file any application, including the Application for Employment Authorization (Form I–765), to maintain their TPS benefits through March 24, 2020, if they have properly re-registered for TPS during the most recent DHS-announced registration period for their country, which ran from May 22, 2018 through July 23, 2018, or the previous re-registration period from October 26, 2016 through December 27, 2016. TPS beneficiaries who have failed to re-register properly for TPS during either of these re-registration periods may still file Form I–821 (Application for Temporary Protected Status) but must demonstrate ''good cause'' for failing to re-register on time, as required by law. *See* INA section 244(c)(3)(C) (TPS beneficiary's failure to register without good cause in form and manner specified by DHS is ground for TPS withdrawal); 8 CFR 244.17(b) and Instructions to Form I–821. Any eligible beneficiary under the TPS designation for Nepal who either does not possess an EAD that is automatically extended by this Notice, or wishes to apply for a new EAD may file Form I–765 with appropriate fee (or fee waiver request). If approved, USCIS will issue an EAD with a March 24, 2020 expiration date. Similarly, USCIS will issue an EAD with a March 24, 2020 expiration date for those with pending EAD applications that are ultimately approved.

Possible Future Action

If it becomes necessary to comply with statutory requirements for TPS re-registration during the pendency of the District Court's Order or any superseding court order concerning the beneficiaries under the TPS designations for Nepal and Honduras, DHS may announce re-registration procedures in a future **Federal Register** Notice. *See* section 244(c)(3)(C) of the INA; 8 CFR 244.17.

Following the conclusion of the appeal of the preliminary injunction in *Ramos* v. *Nielsen,* TPS will remain in effect for Honduras and Nepal for a minimum of the later of (a) 120 days from the issuance of any appellate mandate to the District Court, or (b) on the Secretary's previously-announced effective date for the termination of TPS designations for each individual country, as follows:

- Nepal—N/A; [1]
- Honduras—January 5, 2020.

To the extent that a **Federal Register** Notice has automatically extended TPS-Related Documentation beyond the 120-day period, DHS reserves the right to issue a subsequent **Federal Register** Notice announcing an expiration date for the documentation that corresponds to the last day of the 120-day period. Should the Government move to vacate the stay in proceedings in light of an appellate decision affirming the preliminary injunction in *Ramos* v. *Nielsen* that suggests a basis on which to distinguish the determinations to terminate the TPS designations for Honduras and Nepal TPS from the TPS terminations at issue in *Ramos* v. *Nielsen,* TPS will remain in effect for Honduras and Nepal for at least 180 days following an order of the District Court vacating the stay in proceedings.

Effect on TPS-Related Documentation for Beneficiaries Under the TPS Designation for Honduras

If otherwise eligible, beneficiaries under the TPS designation for Honduras who either have been approved for re-registration or have pending TPS re-registration and EAD applications, either have or will receive TPS-Related Documentation that will remain in effect until January 5, 2020. DHS will issue a **Federal Register** Notice approximately 45 days before January 5, 2020, that will announce an automatic extension of TPS-related documentation for beneficiaries under the TPS designation for Honduras. The automatic extension announced in this Notice therefore does not apply to them.[2]

Additional Notes

Nothing in this Notice affects DHS's ongoing authority to determine on a case-by-case basis whether TPS beneficiaries continue to meet the individual eligibility requirements for TPS described in section 244(c) of the INA and the implementing regulations in part 244 of Title 8 of the Code of Federal Regulations.

Notice of Compliance With Court Order To Stay Proceedings and Agreement To Stay the Determinations Terminate the TPS Designations for Nepal and Honduras

As required by the order of the U.S. District Court for the Northern District of California to stay proceedings in *Bhattarai* v. *Nielsen,* No. 19–cv–00731 (N.D. Cal. Mar. 12, 2019), DHS will not implement or enforce the previously-announced determinations to terminate the existing TPS designations for Nepal and Honduras [3] unless and until the District Court's order in *Ramos* v. *Nielsen* enjoining implementation and enforcement of the determinations to terminate the TPS designations for Sudan, Nicaragua, Haiti, and El Salvador is reversed and that reversal becomes final for some or all of the affected countries, or by other order of the court.

In further compliance with the Order, I am publishing this **Federal Register** Notice automatically extending the validity of the TPS-Related Documentation specified above in the Supplementary Information section of this Notice for nine months through March 24, 2020, for eligible beneficiaries under the TPS designation for Nepal.

Any termination of TPS-Related Documentation for beneficiaries under the TPS designations for Nepal and Honduras will go into effect on the later of: (a) 120 days following the issuance of any mandate to the District Court, or (b) on the Secretary's previously-announced effective date for the termination of TPS designations for each individual country. To the extent that a subsequent **Federal Register** Notice has automatically extended TPS-Related Documentation beyond the 120-day period, DHS reserves the right to issue another **Federal Register** Notice invalidating the documents at the end of the 120-day period. Should the Government move to vacate the stay in proceedings in light of an appellate decision affirming the preliminary injunction in *Ramos* v. *Nielsen* that suggests a basis on which to distinguish the Honduras and Nepal TPS terminations from the TPS terminations at issue in *Ramos* v. *Nielsen,* TPS will remain in effect for Honduras and Nepal for at least 180 days following an order of the court vacating the stay in proceedings.

[1] Any 120-day transition period would end later than the Secretary's previously-announced effective date for the termination of TPS designation for Nepal (June 24, 2019).

[2] *See* Termination of the Designation of Honduras for Temporary Protected Status, 83 FR 26074 (June 5, 2018).

[3] *See* Termination of the Designation of Nepal for Temporary Protected Status, 83 FR 23705 (May 22, 2018); Termination of the Designation of Honduras for Temporary Protected Status, 83 FR 26074 (June 5, 2018).

DHS will continue to issue **Federal Register** Notices that will automatically extend by nine months TPS-Related Documentation for all affected beneficiaries under the TPS designations for Nepal and Honduras, so long as the order to stay proceedings remains in place, or by other order of the court, and will continue its commitment to a transition period, as described above.

All TPS beneficiaries must continue to maintain their TPS eligibility by meeting the requirements for TPS in INA section 244(c) and 8 CFR part 244. DHS will continue to adjudicate any pending TPS re-registration and pending late initial applications for affected beneficiaries under the TPS designations for Nepal and Honduras, and continue to make appropriate individual TPS withdrawal decisions in accordance with existing procedures if an individual no longer maintains TPS eligibility. DHS may continue to announce periodic re-registration procedures for eligible TPS beneficiaries in accordance with the INA and DHS regulations. Should the order to stay proceedings remain in effect, DHS will take appropriate steps to continue its compliance with the order, and all statutory requirements.

Kevin K. McAleenan,

Acting Secretary.

Approved Forms To Demonstrate Continuation of Lawful Status and TPS-Related Employment Authorization

• *This **Federal Register** Notice May 10, 2019*

○ Through operation of this **Federal Register** Notice, certain EADs of affected beneficiaries under the TPS designation for Nepal are automatically extended through March 24, 2020.

○ A beneficiary granted TPS under the designation for Nepal may show his or her specified EAD to his or her employer to demonstrate identity and continued TPS-related employment eligibility for purposes of meeting the Employment Eligibility Verification (Form I–9) requirements. A beneficiary granted TPS under the designation for Nepal may also wish to show an employer this **Federal Register** Notice, which explains that his or her EAD has been automatically extended.

○ Alternatively, such a TPS beneficiary may choose to show other acceptable documents that are evidence of identity and employment eligibility as described in the Instructions to Employment Eligibility Verification (Form I–9).

○ Finally, such a TPS beneficiary may show a copy of this Notice, along with his or her specified EAD, Form I–94, or Form I–797, Notice of Action (Approval Notice), as evidence of his or her lawful status, to law enforcement, federal, state, and local government agencies, and private entities.

• *Employment Authorization Document (EAD)*

Am I eligible to receive an automatic extension of my current EAD through March 24, 2020, using this *Federal Register* notice?

Yes. Provided that you currently have a TPS-related EAD for Nepal with the specified expiration dates described below, this **Federal Register** Notice automatically extends your EAD through March 24, 2020, if you:

• Are a national of Nepal (or an alien having no nationality who last habitually resided in Nepal) who has TPS, and your EAD contains a category code of A–12 or C–19 and one of the expiration dates shown below:

06/24/2018

06/24/2019

When hired, what documentation may I show to my employer as evidence of employment authorization and identity when completing Employment Eligibility Verification (Form I–9)?

You can find the Lists of Acceptable Documents on the third page of Form I–9 as well as the ''Acceptable Documents'' web page at *https://www.uscis.gov/i-9-central/acceptable-documents*. Employers must complete Form I–9 to verify the identity and employment authorization of all new employees. Within three days of hire, employees must present acceptable documents to their employers as evidence of identity and employment authorization to satisfy Form I–9 requirements.

You may present any document from List A (which provides evidence of both identity and employment authorization) or one document from List B (which provides evidence of your identity) together with one document from List C (which is evidence of employment authorization), or you may present an acceptable receipt for List A, List B, or List C documents as described in the Form I–9 Instructions. Employers may not reject a document based on a future expiration date. You can find additional information about Form I–9 on the I–9 Central web page at *http://www.uscis.gov/I-9Central*.

An EAD is an acceptable document under List A.

If your EAD has category code of A–12 or C–19 and an expiration date from the column below, you may show your expired EAD along with this **Federal Register** Notice to complete Form I–9:	Enter this date in Section 1 of Form I–9:	Your employer must reverify your employment authorization by:
June 24, 2018	March 24, 2020	March 25, 2020.
June 24, 2019	March 24, 2020	March 25, 2020.

If you want to use your EAD with one of the specified expiration dates above, and that date has passed, then you may also provide your employer with a copy of this **Federal Register** Notice, which explains that your EAD has been automatically extended for a temporary period of time, through March 24, 2020 (if you are a beneficiary under the TPS designation for Nepal).

What documentation may I present to my employer for Employment Eligibility Verification (Form I–9) if I am already employed but my current TPS-related EAD is set to expire?

Even though your EAD has been automatically extended, your employer is required by law to ask you about your continued employment authorization, and you will need to present your employer with evidence that you are still authorized to work. Once presented, you may correct your employment authorization expiration date in Section 1 and your employer should correct the EAD expiration date in Section 2 of Form I–9. *See* the subsection titled, ''What corrections should my current employer and I make to Employment Eligibility Verification (Form I–9) if my employment authorization has been automatically extended?'' for further information. You may show this **Federal Register** Notice to your employer to explain what to do for Form I–9 and to show that your EAD

has been automatically extended through March 24, 2020 (if you are a beneficiary under the TPS designation for Nepal). Your employer may need to re-inspect your automatically extended EAD to check the expiration date and Category code if your employer did not keep a copy of your EAD when you initially presented it.

The last day of the automatic EAD extension for eligible beneficiaries under the TPS designation for Nepal is March 24, 2020. Before you start work on March 25, 2020, your employer is required by law to reverify your employment authorization in Section 3 of Form I–9. At that time, you must present any document from List A or any document from List C on Form I–9 Lists of Acceptable Documents, or an acceptable List A or List C receipt described in the Form I–9 Instructions to reverify employment authorization. If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9, and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *http://www.uscis.gov/I-9Central* for the most current version of Form I–9.

Your employer may not specify which List A or List C document you must present and cannot reject an acceptable receipt.

Can I seek a new EAD?

You do not need to apply for a new EAD in order to benefit from this automatic extension. However, if you are a beneficiary under the TPS designation for Nepal and want to obtain a new EAD valid through March 24, 2020, you must file an Application for Employment Authorization (Form I–765) and pay the Form I–765 fee (or request a fee waiver). If you do not want a new EAD, you do not have to file Form I–765 or pay the Form I–765 fee. If you do not want to request a new EAD now, you may also file Form I–765 at a later date and pay the fee (or request a fee waiver), provided that you still have TPS or a pending TPS application. You may file the application for a new EAD either before or after your current EAD has expired.

If you are unable to pay the application fee and/or biometric services fee, you may complete a Request for Fee Waiver (Form I–912) or submit a personal letter requesting a fee waiver with satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS web page at *http://www.uscis.gov/tps.* Fees for the Form I–821, the Form I–765, and biometric services are also described in 8 CFR 103.7(b)(1)(i).

If you have a Form I–821 and/or Form I–765 that was still pending as of June 24, 2019, then you should not file either application again. If your pending TPS application under the TPS designation for Nepal is approved, you will be granted TPS through March 24, 2020. Similarly, if you have a pending TPS-related application for an EAD that is approved, it will be valid through the same date.

Can my employer require that I provide any other documentation to prove my status, such as proof of my citizenship from Nepal?

No. When completing Form I–9, including reverifying employment authorization, employers must accept any documentation that appears on the Form I–9 ''Lists of Acceptable Documents'' that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers need not reverify List B identity documents. Employers may not request documentation that does not appear on the ''Lists of Acceptable Documents.'' Therefore, employers may not request proof of citizenship or proof of re-registration for TPS when completing Form I–9 for new hires or reverifying the employment authorization of current employees. If presented with EADs that have been automatically extended, employers should accept such documents as a valid List A document so long as the EAD reasonably appears to be genuine and relates to the employee. Refer to the Note to Employees section of this **Federal Register** Notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

How do my employer and I complete Employment Eligibility Verification (Form I–9) using my automatically extended employment authorization for a new job?

If you are a beneficiary under the TPS designation for Nepal, when using an automatically extended EAD to complete Form I–9 for a new job on or before March 24, 2020, you and your employer should do the following:

1. For Section 1, you should:

a. Check ''An alien authorized to work until'' and enter March 24, 2020, as the ''expiration date''; and

b. Enter your Alien Number/USCIS number or A-Number where indicated (your EAD or other document from DHS will have your USCIS number or A-Number printed on it; the USCIS number is the same as your A-Number without the A prefix).

2. For Section 2, your employer should:

a. Determine if the EAD is automatically extended:

An employee's EAD has been automatically extended if it contains a category code of A–12 or C–19 and an expiration date shown below:
06/24/2018. 06/24/2019.

If it has been automatically extended, the employer should:

b. Write in the document title;

c. Enter the issuing authority;

d. Provide the document number; and

e. Write March 24, 2020, as the expiration date.

Before the start of work on March 25, 2020, employers are required by law to reverify the employee's employment authorization in Section 3 of Form I–9. If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9 and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *http://www.uscis.gov/I-9Central* for the most current version of Form I–9.

What corrections should my current employer and I make to Employment Eligibility Verification (Form I–9) if my employment authorization has been automatically extended?

If you presented a TPS-related EAD that was valid when you first started your job and your EAD has now been automatically extended because you are a beneficiary under the TPS designation for Nepal, your employer may need to re-inspect your current EAD if they do not have a copy of the EAD on file. You may, and your employer should, correct your previously completed Form I–9 as follows:

1. For Section 1, you may:

a. Draw a line through the expiration date in Section 1;

b. Write March 24, 2020, above the previous date; and

c. Initial and date the correction in the margin of Section 1.

2. For Section 2, employers should:

a. Determine if the EAD is automatically extended:

An employee's EAD has been automatically extended if it contains a category code of A–12 or C–19 and an expiration date shown below:
06/24/2018. 06/24/2019.

If it has been automatically extended:

b. Draw a line through the expiration date written in Section 2;

c. Write March 24, 2020, above the previous date; and

d. Initial and date the correction in the Additional Information field in Section 2.

Note: This is not considered a reverification. Employers do not need to complete Section 3 until either this Notice's automatic extension of EADs has ended or the employee presents a new document to show continued employment authorization, whichever is sooner. By March 25, 2020, when the employee's automatically extended EAD has expired, employers are required by law to reverify the employee's employment authorization in Section 3. If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9 and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *http://www.uscis.gov/I-9Central* for the most current version of Form I–9.

If I am an employer enrolled in E-Verify, how do I verify a *new* employee whose EAD has been automatically extended?

Employers may create a case in E-Verify for these employees by providing the employee's Alien Registration number (A#) or USCIS number as the document number on Form I–9 in the document number field in E-Verify.

If I am an employer enrolled in E-Verify, what do I do when I receive a ''Work Authorization Documents Expiration'' alert for an automatically extended EAD?

If you have employees who provided a TPS-related EAD with an expiration date that has been automatically extended by this Notice, you should dismiss the ''Work Authorization Documents Expiring'' case alert. Before this employee starts to work on March 25, 2020, you must reverify his or her employment authorization in Section 3 of Form I–9. Employers should not use E-Verify for reverification.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This **Federal Register** Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* USCIS accepts calls and emails in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process (Form I–9 and E-Verify), employers may call the U.S. Department of Justice's Civil Rights Division, Immigrant and Employee Rights Section (IER) (formerly the Office of Special Counsel for Immigration-Related Unfair Employment Practices) Employer Hotline at 800–255–8155 (TTY 800–237–2515). IER offers language interpretation in numerous languages. Employers may also email IER at *IER@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* USCIS accepts calls in English, Spanish, and many other languages. Employees or applicants may also call the IER Worker Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship, immigration status, or national origin, including discrimination related to Employment Eligibility Verification (Form I–9) and E-Verify. The IER Worker Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt as described in the Employment Eligibility Verification (Form I–9) Instructions. Employers may not require extra or additional documentation beyond what is required for Form I–9 completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from an employee's Form I–9 differs from records available to DHS.

Employers may not terminate, suspend, delay training, withhold pay, lower pay, or take any adverse action against an employee because of the TNC while the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). For more information about E-Verify-related discrimination or to report an employer for discrimination in the E-Verify process based on citizenship, immigration status, or national origin, contact IER's Worker Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Form I–9 and E-Verify procedures is available on the IER website at *https://www.justice.gov/ier* and on the USCIS and E-Verify websites at *https://www.uscis.gov/i-9-central* and *https://www.e-verify.gov.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, state and local government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, state, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary, show you are authorized to work based on TPS or other status, and/or that may be used by DHS to determine whether you have TPS or other immigration status. Examples of such documents are:

(1) Your current EAD;

(2) Your automatically extended EAD with a copy of this **Federal Register** Notice, providing an automatic extension of your currently expired or expiring EAD;

(3) A copy of your Form I–94, (Arrival/Departure Record), or Form I–797, Notice of Action (Approval Notice), that has been automatically extended by this Notice and a copy of this Notice;

(4) Any other relevant DHS-issued document that indicates your immigration status or authorization to be in the United States, or that may be used by DHS to determine whether you

have such status or authorization to remain in the United States.

Check with the government agency regarding which document(s) the agency will accept.

Some benefit-granting agencies use the SAVE program to confirm the current immigration status of applicants for public benefits. While SAVE can verify when an individual has TPS, each agency's procedures govern whether they will accept an automatically extended TPS-related document. You should present the agency with a copy of this **Federal Register** Notice showing the extension of TPS-related documentation in addition to your recent TPS-related document with your alien or I–94 number. You should explain that SAVE will be able to verify the continuation of your TPS using this information. You should ask the agency to initiate a SAVE query with your information and follow through with additional verification steps, if necessary, to get a final SAVE response showing the TPS. You can also ask the agency to look for SAVE notices or contact SAVE if they have any questions about your immigration status or automatic extension of TPS-related documentation. In most cases, SAVE provides an automated electronic response to benefit-granting agencies within seconds, but, occasionally, verification can be delayed. You can check the status of your SAVE verification by using CaseCheck at the following link: *https://save.uscis.gov/casecheck/,* then by clicking the ''Check Your Case'' button. CaseCheck is a free service that lets you follow the progress of your SAVE verification using your date of birth and one immigration identifier number. If an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found on the SAVE website at *http://www.uscis.gov/save.*

[FR Doc. 2019–09635 Filed 5–9–19; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6104–N–02]

Announcement of the Housing Counseling Federal Advisory Committee; Notice of Public Meeting

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice of Housing Counseling Federal Advisory Committee public meeting.

SUMMARY: This gives notice of a Housing Counseling Federal Advisory Committee (HCFAC) meeting and sets forth the proposed agenda. The Committee meeting will be held on Wednesday, May 22, 2019. The meeting is open to the public and is accessible to individuals with disabilities. This notice is being published less than 15 days prior to the meeting date due to unforeseen administrative delays.

DATES: The meeting will be held on Wednesday, May 22, 2019 starting at 9:00 a.m. Eastern Daylight Time (EDT) at HUD Headquarters, 451 7th Street SW, Washington, DC 20410 and via teleconference.

FOR FURTHER INFORMATION CONTACT: Virginia F. Holman, Housing Specialist, Office of Housing Counseling, U.S. Department of Housing and Urban Development, 600 East Broad Street, Richmond VA 23219; telephone number 540–894–7790 (this is not a toll-free number); email *virginia.f.holman@hud.gov.* Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Relay at 1–800–877–8339. Individuals may also email *HCFACCommittee@hud.gov.*

SUPPLEMENTARY INFORMATION: HUD is convening the meeting of the HCFAC on Wednesday, May 22, 2019 from 9:00 a.m. to 4:00 p.m. ET. The meeting will be held at HUD Headquarters, 451 7th Street SW, Washington, DC 20410 and via teleconference at 1–800–231–0316, Passcode 1519. This meeting notice is provided in accordance with the Federal Advisory Committee Act, 5. U.S.C. App. 10(a)(2).

Draft Agenda—Housing Counseling Federal Advisory Committee Meeting—May 22, 2019

I. Welcome
II. Advisory Committee Discussion
III. Public Comment
IV. Next Steps
V. Adjourn

Registration

The public is invited to attend this one-day meeting in-person or by phone. Advance registration is required to participate. To register to attend, please visit the following link: *https://pavr.wufoo.com/forms/z41lur512g70uy/.*

After completing the pre-registration process at the above link, in-person attendees will receive details about the meeting location and how to access the building. Call-in participants will be asked by an operator to provide their names and their organizational affiliations (if applicable) to ensure they are part of the pre-registration list. Callers can expect to incur charges for calls they initiate over wireless lines and HUD will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number. Individuals with speech or hearing impairments may follow the discussion by first calling the toll-free Federal Relay FRS: 1–800–977–8339 and provide the operator with the conference call number: 1–800–231–0316, Passcode: 1519.

Comments

With advance registration, members of the public will have an opportunity to provide oral and written comments relative to agenda topics for the Committee's consideration. To provide oral comments, please be sure to indicate this on the registration link. The total amount of time for oral comments will be 15 minutes with each commenter limited to two minutes to ensure pertinent Committee business is completed. Written comments must be provided no later than May 15, 2019 to *HCFACCommittee@hud.gov.* Please note, written statements submitted will not be read during the meeting. The Committee will not respond to individual written or oral statements however, it will take all public comments into account in its deliberations.

Meeting Records

Records and documents discussed during the meeting, as well as other information about the work of this Committee, will be available for public viewing as they become available at: *https://www.facadatabase.gov/FACA/apex/FACAPublicCommittee?id=a10t0000001gzvQAAQ.Information* on the Committee is also available on HUD Exchange at: *https://www.hudexchange.info/programs/housing-counseling/federal-advisory-committee/.*

Dated: May 6, 2019.

John L. Garvin,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2019–09674 Filed 5–9–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–ES–2019–N059; FXES11130500000–190–FF05E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before June 10, 2019.

ADDRESSES: Use one of the following methods to request documents or submit comments. Requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TE123456):

- *Email: permitsR5ES@fws.gov.*
- *U.S. Mail:* Abby Gelb, Ecological Services, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035.

FOR FURTHER INFORMATION CONTACT: Abby Gelb, 413–253–8212 (phone), or *permitsR5ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE37631D	Helen Hays, dba American Museum of Natural History, NY.	Roseate tern (*Sterna dougallii dougallii*).	New York	Survey, monitor	Capture, band ...	New.
TE37632D	USDA Forest Service, Monongahela National Forest, WV.	Candy darter (*Etheostoma osburni*).	West Virginia	Survey, monitor	Electrofish, capture, handle.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martin Miller,

Chief, Division of Endangered Species, Ecological Services, Northeast Region.

[FR Doc. 2019–09620 Filed 5–9–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX19EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal Advisory Committee meeting of the National Geospatial Advisory Committee (NGAC) will take place.

DATES: The meeting will be held on Tuesday, June 11, 2019 from 8:30 a.m. to 5:00 p.m., and on Wednesday, June

12, 2019 from 8:30 a.m. to 4:00 p.m. (Eastern Standard Time).

ADDRESSES: The meeting will be held at the Department of the Interior building, 1849 C Street NW, Washington, DC 20240 in the South Penthouse Conference Room. Send your comments to Group Federal Officer by email to *gs-faca-mail@usgs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. John Mahoney, Federal Geographic Data Committee (FGDC), U.S. Geological Survey (USGS), 909 First Avenue, Suite 800, Seattle, WA 98104; by email at *jmahoney@usgs.gov;* or by telephone at (206) 220–4621.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act 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: The National Geospatial Advisory Committee (NGAC) provides advice and recommendations related to the management of Federal and national geospatial programs, the development of the National Spatial Data Infrastructure, and the implementation of the Geospatial Data Act of 2018 and Office of Management and Budget Circular A–16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC meeting is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC meeting is available at: *www.fgdc.gov/ngac.*

Agenda Topics

—FGDC Update
—Geospatial Data Act Implementation
—Cultural and Historical Geospatial Resources
—Geospatial Infrastructure
—Landsat Advisory Group

Meeting Accessibility/Special Accommodations: The meeting is open to the public from 8:30 a.m. to 5:00 p.m. on June 11 and from 8:30 a.m. to 4:00 p.m. on June 12. Members of the public wishing to attend the meeting should contact Ms. Lucia Foulkes by email at *lfoulkes@usgs.gov* to register no later than five (5) business days prior to the meeting. Seating may be limited due to room capacity. Individuals requiring special accommodations to access the public meeting should contact Ms. Lucia Foulkes at the email stated above or by telephone at 703–648–4142 at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Public Disclosure of Comments: Time will be allowed at the meeting for any individual or organization wishing to make formal oral comments. To allow for full consideration of information by the committee members, written notice must be provided to Ms. Lucia Foulkes, Federal Geographic Data Committee (FGDC), U.S. Geological Survey, 12201 Sunrise Valley Drive, MS–590, Reston, VA 20192; by email at *lfoulkes@usgs.gov;* or by telephone at 703–648–4142, at least five (5) business days prior to the meeting. Any written comments received will be provided to the committee members.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Kenneth M. Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2019–09669 Filed 5–9–19; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0111]

Agency Information Collection Activities; Payment for Appointed Counsel in Involuntary Indian Child Custody Proceedings in State Courts

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, Bureau of Indian Affairs (BIA) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before July 9, 2019.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to the Mrs. Evangeline M. Campbell, 1849 C Street NW, Mail Stop 4513, Washington, DC 20240; fax: (202) 513–208–5113; email: *Evangeline.Campbell@bia.gov.* Please reference OMB Control Number 1076–0111 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mrs. Evangeline M. Campbell, (202) 513–7621.

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 the BIA; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIA enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIA 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: The BIA is seeking renewal of the approval for the information collection conducted under 25 CFR 23.13, implementing the Indian Child Welfare Act (25 U.S.C. 1901 *et seq.*). The information collection allows BIA to receive written requests by State courts that appoint counsel for an indigent Indian parent or Indian custodian in an involuntary Indian child custody proceeding when appointment of counsel is not authorized by State law. The applicable BIA Regional Director

uses this information to decide whether to certify that the client in the notice is eligible to have his counsel compensated by the BIA in accordance with the Indian Child Welfare Act.

Title of Collection: Payment for Appointed Counsel in Involuntary Indian Child Custody Proceedings in State Courts.

OMB Control Number: 1076–0111.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State courts.

Total Estimated Number of Annual Respondents: Two per year.

Total Estimated Number of Annual Responses: Two per year.

Estimated Completion Time per Response: Two hours for reporting and one hour for recordkeeping.

Total Estimated Number of Annual Burden Hours: Six hours.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $0.

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.*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2019–09641 Filed 5–9–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM921200.L13200000.PP0000. 19XL1109AF]

Notice of Availability of the Environmental Assessment for Evans McCurtain Federal Coal Lease-by-Application OKNM127509, Haskell and LeFlore Counties, OK, Notice of Public Hearing, and Request for Comment on Environmental Assessment, Maximum Economic Recovery, and Fair Market Value; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice; correction.

SUMMARY: The Bureau of Land Management (BLM) published a notice in the **Federal Register** on December 27, 2018, announcing the availability of an environmental assessment (EA) and the public comment period and public hearing for a proposed Federal Coal Lease-by-Application (LBA). The notice published during the period of partial government shutdown and therefore the public hearing was canceled. This notice announces a corrected public comment period and public hearing date. In addition to the new comment period, the BLM will accept all comments submitted as directed during the prior comment period announced by the December 27, 2018, **Federal Register** notice.

FOR FURTHER INFORMATION CONTACT: April Crawley, BLM Natural Resource Specialist, BLM Oklahoma Field Office, 201 Stephenson Parkway, Norman, OK 73072; *blm_nm_ok_coal@blm.gov;* 405–579–7171. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** notice published on December 27, 2018 (83 FR 66743), in the second column, correct the **DATES** caption to read:

DATES: The public hearing will be held on Thursday, May 30, 2019, from 5 p.m.–7 p.m. Written comments should be received no later than June 10, 2019.

In the second column, correct the first sentence of the **ADDRESSES** caption to read:

ADDRESSES: The public hearing will be held at McCurtain City Hall, 308 Main Street, McCurtain, OK 74944.

In the second column of page 66744, correct the first sentence of the fifth paragraph to read:

Please send written comments on the LBA EA, MER, and FMV to April Crawley at the address listed in the **ADDRESSES** section in the notice or through ePlanning, as described above, prior to close of business June 10, 2019.

Timothy R. Spisak,

BLM New Mexico State Director.

[FR Doc. 2019–08771 Filed 5–9–19; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOS00000–L12200000.DF0000–19X]

Notice of Public Meetings, Southwest (Colorado) Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Southwest (Colorado) Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Southwest RAC has scheduled its meetings for June 13, 2019 and September 25, 2019. Each meeting will begin at 8 a.m. and adjourn at approximately 3:00 p.m.

ADDRESSES: The June 13, 2019 meeting will be held in Grand Junction at the BLM Grand Junction Field Office, 2815 H Road; the September 25, 2019 meeting will held in Dolores at the Dolores Public Lands Office, 29211 Hwy 184.

FOR FURTHER INFORMATION CONTACT: Gloria Tibbetts, Associate District Manager, Southwest District Office, 2465 South Townsend Avenue, Montrose, Colorado 81401. Phone: (970) 240–5430. Email: *gtibbetts@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Southwest Colorado RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of public land issues in the Southwest District, including the Grand Junction, Uncompahgre and Tres Rios field offices. Topics of discussion for these meetings include recreation, recreation fee proposals, fire management, land use planning, invasive species management, energy and minerals management, travel management, wilderness, wild horse herd management, land exchange proposals, cultural resource management, and other issues as appropriate. Final agendas will be posted online at *https://www.blm.gov/get-involved/resource-*

advisory-council/near-you/colorado/southwest-rac.

The June 13, 2019, agenda includes a Special Recreation Permit program overview, a proposal to improve camping opportunities in the Rabbit Valley area of the McInnis Canyons National Conservation Area, a right-of-way proposal in the Domiguez-Escalante National Conservation Area and a discussion about establishing a RAC subcommittee for Jumbo Mountain in Delta County.

The meetings are open to the public, and each meeting will offer a 30 minute public comment period. Depending on the number of persons wishing to comment and the time available, time allotted for individual oral comments may be limited. The public may also send written comments to Gloria Tibbetts (see **FOR FURTHER INFORMATION CONTACT**). All comments received will be provided to the Southwest RAC.

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.

Detailed meeting minutes for the Southwest RAC meetings will be maintained in the Southwest District Office and will be available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting. Previous minutes, membership information and upcoming agendas are available at: *https://www.blm.gov/get-involved/resource-advisory-council/near-you/colorado/southwest-rac.*

Authority: 43 CFR 1784.4–2.

Gregory P. Shoop,

BLM Colorado Associate State Director.

[FR Doc. 2019–09697 Filed 5–9–19; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00000L16100000. DX000019XMO#4500129833]

Notice of Termination of RMP Revision for the Las Vegas and Pahrump Field Offices, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of termination.

SUMMARY: The preparation of an Environmental Impact Statement (EIS) for the Resource Management Plan (RMP) Revision for the Las Vegas and Pahrump Field Offices is hereby terminated.

DATES: Preparation of a revised EIS for the Las Vegas and Pahrump Field Offices RMP is terminated immediately.

FOR FURTHER INFORMATION CONTACT: Lee Kirk, RMP Project Manager, (702) 515–5026, or email *jkirk@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Pursuant to the National Environmental Policy Act of 1969, as implemented by the Council on Environmental Quality regulations, the Bureau of Land Management (BLM) announced its intent to prepare an EIS with publication of a Notice of Intent on January 5, 2010, in the **Federal Register** (75 FR 428). The purpose of the EIS was to update the existing Las Vegas RMP approved in 1998. The Notice of Availability for the Draft EIS was published in the **Federal Register** on October 10, 2014 (79 FR 61334). The Draft EIS was distributed to various Federal, State, and local agencies, elected officials, special interest groups, interested individuals, and the media. Public input meetings were held on November 3, 5, 6, 12, and 13, 2014. Due to new legislation enacted and RMP amendments completed since the EIS process was initiated in 2010, the BLM decided to continue management of the public lands in the Las Vegas and Pahrump planning area (Southern Nevada District Office) under the existing RMP (as amended) and to consider additional plan amendments on a case-by-case basis, as needed. The issues initially identified can be resolved through smaller, focused RMP amendments rather than an RMP revision. Therefore, the BLM hereby terminates the preparation of an RMP Revision and associated EIS for the Las Vegas and Pahrump Field Offices, in the BLM Southern Nevada District.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

Brian C. Amme,

Acting State Director.

[FR Doc. 2019–09696 Filed 5–9–19; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCAC09000 L16100000.DF000 19XL; MO#4500122590]

Notice of Availability of the Central Coast Field Office Proposed Resource Management Plan Amendment and Final Environmental Impact Statement for Oil and Gas Leasing and Development, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a proposed Resource Management Plan (RMP) amendment and Final Environmental Impact Statement (EIS) for oil and gas leasing and development within the boundaries of the Central Coast Field Office, and by this notice is announcing its availability.

DATES: The BLM planning regulations state that any person who meets the conditions as described in the regulations may protest the BLM's proposed RMP amendment and Final EIS. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency (EPA) publishes its Notice of Availability in the **Federal Register**.

ADDRESSES: Copies of the proposed RMP amendment and Final EIS have been sent to affected Federal, State, local, and tribal government agencies and to other stakeholders. Copies of the proposed RMP amendment and Final EIS are available for public inspection at the BLM Central Coast Field Office at 940 2nd Ave., Marina, CA 93933. Interested persons may also review the proposed RMP amendment and Final EIS on the internet at *https://go.usa.gov/xEGQC.*

All protests must be in writing (43 CFR 1610.5–2(a)(1)) and filed with the BLM Director, either as a hard copy or electronically via the BLM's ePlanning project website. To file a protest electronically, visit *https://go.usa.gov/xEGQC.* Protests in hard copy must be postmarked no more than 30 days after the date the EPA publishes its Notice of Availability of the Final EIS in the **Federal Register** and must be mailed to one of the following addresses:

Regular Mail: BLM Director (210), Attention: Protest Coordinator, P.O. Box 71383, Washington, DC 20024–1383.

Overnight Delivery: BLM Director (210), Attention: Protest Coordinator, 20 M Street SE, Room 2134LM, Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: Sky Murphy, BLM Planning and Environmental Coordinator, telephone (831) 582–2200; address Bureau of Land Management, Central Coast Field Office, 940 2nd Ave., Marina, CA 93933; or email *blm_ca_ogeis@blm.gov.*

Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact Sky Murphy during normal business hours. FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Central Coast Field Office proposed RMP amendment and Final EIS describes and analyzes alternatives for the planning and management of oil and gas leasing and development on public lands and Federal mineral estate managed by the BLM Central Coast Field Office. The former Hollister Field Office moved to Marina, California, and is now called the Central Coast Field Office. The planning area is located in central California and comprises approximately 6.8 million acres of land. Within the planning area, the BLM manages approximately 300,000 acres of surface estate and approximately 800,000 acres of subsurface Federal mineral estate. Planning decisions in the proposed RMP amendment will apply only to the BLM-managed public lands and Federal mineral estate in the planning area.

Through this planning process, the BLM is revising the ''2007 Resource Management Plan for the Southern Diablo Mountain Range and Central Coast of California'' to analyze the effects of alternative oil and gas management approaches on public lands and Federal mineral estate. The proposed RMP amendment/Final EIS also includes implementation-level analysis regarding 14 leases that were the subject of litigation in 2011 and 2012.

In 2014, the BLM conducted scoping to solicit input from the public and interested agencies on the nature and extent of issues and impacts to be addressed. Fifteen issues were identified through the scoping process: (1) Water resources; (2) Health and safety; (3) Vegetation and wildlife; (4) Air quality; (5) Climate change; (6) Geology and seismicity; (7) Soil resources; (8) Socioeconomics; (9) Traffic; (10) Tribal and cultural resources; (11) Environmental justice; (12) Land use; (13) Livestock grazing; (14) Recreation; and (15) Visual resources.

To assist the agency decision maker and the public in focusing on appropriate solutions to planning issues, the proposed RMP amendment and Final EIS considers six management alternatives.

Alternative A. Alternative A would continue current management under the existing RMP. All Federal mineral estate would be available for oil and gas leasing, except for designated wilderness, wilderness study areas, the Fort Ord National Monument, and the Clear Creek Serpentine Area of Critical Environmental Concern (ACEC), which are closed under the existing RMP. No Surface Occupancy (NSO) stipulations would be applied in ACECs and to Recreation and Public Purpose (R&PP) leases. The Endangered Species stipulation from the existing RMP would apply in all areas open to leasing.

Alternative B. Under Alternative B, Federal mineral estate within the boundaries of oil and gas fields plus a 0.5-mile buffer currently identified by the California Division of Oil, Gas, and Geothermal Resources (DOGGR) would be available for leasing. Other areas would be closed to oil and gas leasing, including all National Conservation Lands. Controlled Surface Use (CSU) stipulations would apply to all lands open to leasing.

Alternative C. Under Alternative C, unless currently closed under the existing RMP, Federal mineral estate would be open to leasing within high oil and gas potential areas or within 0.5-mile of the boundaries of oil and gas fields currently identified by DOGGR, with the exception of core population areas of the giant kangaroo rat in the vicinity of Panoche, Griswold-Tumey and Ciervo Hills, which would be closed to leasing. CSU stipulations would apply to all lands open to leasing. NSO stipulations would apply to some lands open to leasing, including: (1) Threatened and endangered species critical habitat; (2) BLM-developed recreation and administrative sites; and (3) Special status split estate lands (*e.g.,* State parks, county parks, lands with existing conservation easements, land trusts and scenic designations).

Alternative D. Under Alternative D, unless currently closed under the existing RMP, Federal mineral estate underlying BLM surface estate would be available for leasing. All Federal mineral estate underlying the Ciervo Panoche Natural Area (both BLM surface and split-estate lands) would be closed to leasing. CSU stipulations would apply to all lands open to leasing. NSO stipulations would be applied in ACECs and R&PP leases.

Alternative E. Under Alternative E, unless currently closed under the existing RMP, Federal mineral estate outside of a California Department of Water Resources Bulletin 118, Groundwater Basin or Sub-basin, would be available for leasing. CSU stipulations would apply to all lands open to leasing. NSO stipulations would apply to some lands open to leasing, including: (1) 12-digit Hydrologic Unit Codes (HUCs) intersecting EPA impaired, perennial surface waters (BLM surface and split estate); (2) 12-digit HUCs intersecting non-impaired, perennial surface waters that intersect split estate; (3) 12-digit HUC sub-watersheds with the highest aquatic intactness score; (4) 0.25 miles from non-impaired, perennial surface waters; and (5) 0.25 miles from eligible Wild and Scenic Rivers.

Alternative F (Preferred Alternative). Under Alternative F, all Federal mineral estate would be available for oil and gas leasing with CSU stipulations, except for designated wilderness, wilderness study areas, the Fort Ord National Monument, and the Clear Creek Serpentine ACEC, which are closed under the existing RMP. NSO stipulations would be applied in the Joaquin Rocks ACEC, as well as within ACECs and giant kangaroo rat core population areas in the Ciervo Panoche Natural Area. Under each action alternative, CSU stipulations would apply to all lands open to leasing. The CSU stipulations would mitigate impacts to sensitive resources such as protected, sensitive and priority species, critical and priority habitat, cultural resources, and water resources by requiring special operational constraints on surface use to protect these resources.

There are three ACECs managed by the CCFO: The Clear Creek Serpentine ACEC is approximately 31,000 acres; the Panoche/Coalinga ACEC is approximately 56,000 acres: And the Joaquin Rocks ACEC is approximately 8,000 acres. No boundaries of these ACECs are being modified by this proposed RMP amendment.

The proposed RMP amendment and Final EIS also addresses two leases and 12 prospective leases within the CCFO that do not contain NSO stipulations (non-NSO leases), pursuant to a July 2014, Federal court settlement agreement to resolve the disputes set forth in *Center for Biological Diversity and Sierra Club* v. *Bureau of Land*

Management, et al., Case No. 11–06174 and Case No. 13–1749 (N.D. Cal.). The BLM's proposed plan identifies implementation-level decisions for these 14 issued and prospective leases. For each of the 14 leases, the implementation decision will determine whether the leases would be issued and identify stipulations necessary for resource protection. These implementation-level decisions are subject to appeal to the Interior Board of Land Appeals after the signing of a Record of Decision for this project.

Public comments on the draft RMP amendment and Draft EIS received from the public and internal BLM review in 2017 were considered and incorporated, as appropriate into the proposed plan. As a result of comments, the BLM developed and analyzed Alternative F to be consistent with the BLM's land use planning and energy development policies. Public comments resulted in the addition of clarifying text in the Final EIS.

Instructions for filing a protest with the Director of the BLM regarding the proposed RMP amendment and Final EIS may be found in the ''Dear Reader'' letter of the Central Coast Field Office proposed RMP amendment and Final EIS and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section earlier or submitted electronically through the BLM ePlanning project website as described earlier. Protests submitted electronically by any means other than the ePlanning project website protest section will be invalid unless a protest is also submitted in hard copy. Protests submitted by fax will also be invalid unless also submitted either through ePlanning project website protest section or in hard copy.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.5)

Danielle Chi,

Deputy State Director, Fire and Resources.

[FR Doc. 2019–09599 Filed 5–9–19; 8:45 am]

BILLING CODE 4310–40–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–017]

Cancellation Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

ORIGINAL TIME AND DATE: May 9, 2019 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR 201.37(a), the Commission hereby gives notice that the Commission has determined to cancel the meeting scheduled for May 9, 2019 at 9:30 a.m.

Earlier notification of this cancellation was not possible.

By order of the Commission.

Issued: May 8, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–09836 Filed 5–8–19; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–990 (Third Review)]

Non-Malleable Cast Iron Pipe Fittings From China; Scheduling of an Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on non-malleable cast iron pipe fittings from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: April 12, 2019.

FOR FURTHER INFORMATION CONTACT: Junie Joseph (205–202–3363), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On April 12, 2019, the Commission determined that the domestic interested party group response to its notice of institution (84 FR 14, January 2, 2019) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).[2]

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on May 15, 2019, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[3] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before May 21, 2019 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] Commissioners Johanson and Broadbent voted to conduct full reviews.

[3] The Commission has found the responses submitted by Anvil International, LLC and Ward Manufacturing LLC to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

contain any new factual information) pertinent to the review by May 21, 2019. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules with respect to filing were revised effective July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's website at *https://edis.usitc.gov.*

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: May 7, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–09672 Filed 5–9–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Mobile Alliance

Notice is hereby given that, on April 26, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Mobile Alliance (''OMA'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Advantech B&B Smartworx, Oranmore, IRELAND; American Innovations, Austin, TX; Carota Corporation, Shanghai, PEOPLE'S REPUBLIC OF CHINA; IOTECC, Uoblenz, GERMANY; Polaris Wireless, Mountain View, CA; RETHING IoT Technologies PC, Chalandri, GREECE; and Traxens, Marseille, FRANCE, have been added as parties to this venture.

Also, Centero, LLC, Marietta, GA; China Mobile Communications Corporation, Beijing, PEOPLE'S REPUBLIC OF CHINA; ControlBEAM Digital Automation, Ontario, CANADA; Eaton Corporation, Cleveland, OH; GreenWave Systems, Inc., Irvine, CA; HaoLianShiDai (Beijing) Technology Co., Ltd., Beijing, PEOPLE'S REPUBLIC OF CHINA; KDDI Corporation, Tokyo, JAPAN; Motorola Solutions, Inc., Schaumburg, IL; Runtime, Redwood City, CA; Silicon Labs, Inc., Montreal, CANADA; STMicroelectronics, Plan-les-Quates, Geneva, SWITZERLAND; and Vodafone Group Services GmbH, Newberry, UNITED KINGDOM, have withdrawn as parties to this venture.

The following members have changed their names: NewNet Communication Technologies, Inc. to SigMast Communications, Bedford, CANADA; and Softbank Mobile Corp. to Softbank Corp., Tokyo, JAPAN.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OMA intends to file additional written notifications disclosing all changes in membership.

On March 18, 1998, OMA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 31, 1998 (63 FR 72333).

The last notification was filed with the Department on May 2, 2018. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 5, 2018 (83 FR 26092).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–09623 Filed 5–9–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On April 29, 2019, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Hawaii in the lawsuit entitled *United States and State of Hawaii Department of Health* v. *Waste Management Hawaii, Inc. and City and County of Honolulu,* Civil Action No. 19–cv–00224.

The United States and the State of Hawaii Department of Health filed this lawsuit under the Clean Water Act and Hawaii State law. The complaint seeks penalties and injunctive relief for discharges of pollutants, including contaminated storm water and solid waste, from the Waimanalo Gulch Sanitary Landfill located in Oahu, Hawaii. The landfill is operated by defendant Waste Management of Hawaii, Inc., and owned by defendant the City and County of Honolulu. The proposed Consent Decree requires the Defendants to perform injunctive relief to improve storm water management and address effluent limit violations at the landfill. The proposed Consent Decree also requires payment of civil penalties to the United States of $150,000 by Waste Management of Hawaii, Inc., and $62,500 by the City and County of Honolulu. The proposed Consent Decree further requires payments to the Hawaii State Department of Land and Natural Resources of $150,000 by Waste Management of Hawaii, Inc., and $62,500 by the City and County of Honolulu, with these funds to be used for research and restoration of coral and coral habitat.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Hawaii Department of Health* v. *Waste Management Hawaii, Inc. and City and County of Honolulu,* D.J. Ref. No. 90–5–1–1–10729. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*

To submit comments:	Send them to:
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $14.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–09659 Filed 5–9–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Division of Federal Employees' Compensation; Proposed Extension of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Claim for Reimbursement—Assisted Reemployment (CA–2231). A copy of the proposed information collection request can be obtained by contacting the office listed below in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before July 9, 2019.

ADDRESSES: You may submit comments by mail, delivery service, or by hand to Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210; by fax, (202) 354–9647, or email to *ferguson.yoon@dol.gov*. Please use only one method of transmission for comments (mail/delivery, fax, or email). Please note that comments submitted after comment period will not be considered.

SUPPLEMENTARY INFORMATION

I. Background: The Office of Workers' Compensation Programs (OWCP) administers the Federal Employees' Compensation Act (FECA) under 5 U.S.C. 8101 *et seq.* Section 8104(a) of the FECA provides vocational rehabilitation services to eligible injured workers to facilitate their return to work. The costs of providing these vocational rehabilitation services are paid from the Employees' Compensation Fund. Annual appropriations language (currently in Pub. L. 114–113), provides OWCP with legal authority to use amounts from the Fund to reimburse private sector employers for a portion of the salary of reemployed FECA claimants hired through OWCP's assisted reemployment program. Information collected on Form CA–2231 provides OWCP with the necessary remittance information for the employer, documents the hours of work, certifies the payment of wages to the claimant for which reimbursement is sought, and summarizes the nature and costs of the wage reimbursement program for a prompt decision by OWCP. This information collection is currently approved for use through September 30, 2019.

II. Review Focus: The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions: The Department of Labor seeks extension of approval to collect this information to ensure timely and accurate payments to eligible employers for reimbursement claims.

Type of Review: Extension.

Agency: Office of Workers' Compensation Programs.

Title: Claim for Reimbursement-Assisted Reemployment.

OMB Number: 1240–0018.

Agency Number: CA–2231.

Affected Public: Business or other for-profit, Not-for-profit institutions.

Total Respondents: 64.

Total Annual Responses: 128.

Average Time per Response: 30 minutes.

Estimated Total Burden Hours: 32.

Frequency: Quarterly.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $37.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 6, 2019.

Yoon Ferguson,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2019–09640 Filed 5–9–19; 8:45 am]

BILLING CODE 4510–CH–P

NATIONAL SCIENCE FOUNDATION (NSF)

Sunshine Act Meetings; National Science Board

The National Science Board (NSB), pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of NSB business as follows:

TIME AND DATE: Tuesday, May 14, 2019 from 8:00 a.m. to 3:55 p.m., and Wednesday, May 15, 2019 from 9:00 a.m. to 2:45 p.m. EST.

PLACE: These meetings will be held at the NSF headquarters, 2415 Eisenhower

Avenue, Alexandria, VA 22314. Meetings are held in the boardroom on the 2nd floor. The public may observe public meetings held in the boardroom. All visitors must contact the Board Office (call 703–292–7000 or send an email to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the meeting and provide your name and organizational affiliation. Visitors must report to the NSF visitor's desk in the building lobby to receive a visitor's badge.

STATUS: Some of these meetings will be open to the public. Others will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Tuesday, May 14, 2019

Plenary Board Meeting

Open Session: 8:00–8:30 a.m.

- NSB Chair's Opening Remarks
- NSF Director's Remarks
- Summary of Activities
- Creation of *Vision 2030* Task Force

Committee on Awards and Facilities (A&F)

Open Session: 8:30–9:15 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Calendar year (CY) 2019 Schedule of Planned Action and Information Items
- A&F Retreat Report Out
- National Ecological Observatory Network Update

Committee on Awards and Facilities (A&F)

Closed Session: 9:15–10:30 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Action Item: Leadership-Class Computing Facility Operations and Maintenance
- Action Item: Green Bank Observatory Record of Decision
- National Ecological Observatory Network Q & A

Committee on External Engagement (EE)

Open Session: 10:45–11:15 a.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- NSB Alumni Communication Network
- NSB Home District Office Meetings
- New NSB Videos

Plenary Board

Open Session: 11:15–12:00 p.m.

- NSB Chair's Opening Remarks
- Director's Introduction of Dr. Dionne
- Chair's Introduction of Dr. Massey

Plenary Board

Open Session: 1:00–1:45 p.m.

- NSB Chair's Opening Remarks
- Chair's Introduction of Dr. Schaal
- Director's Introduction of Dr. Doeleman

Committee on Strategy (CS)

Open Session: 1:45–3:00 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Update on Budgets
- Presentation on Big Ideas
- Presentation on the Federal STEM Education Strategic Plan

Committee on National Science and Engineering Policy (SEP)

Open Session: 3:15–3:55 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior SEP Minutes
- Update on Reviews of Thematic Reports 1–3 of *SEI 2020*
- Update on Distribution Schedule of Thematic Reports 4–8
- Presentation and Discussion on the Thematic Reports Approval Process
- Update on Title and Cover Image for the ''Summary Report''
- Update on the Reimagined *Indicators* Pre-release Communications Plan

Wednesday, May 15, 2019

Committee on Oversight (CO)

Open Session: 9:00–10:15 a.m.

- Committee Chair's Opening Remarks
- Approval of Committee Meeting Minutes
- Merit Review Report Update
- Review and Recommendation for Transmittal of OIG Semiannual Report and Approval of NSF Management Response
- Inspector General's Update
- Chief Financial Officer's Update

Task Force on the Skilled Technical Workforce (STW TF)

Open Session: 10:30–11:30 a.m.

- Task Force Chair's Opening Remarks
- Approval of Prior Meeting Minutes
- NSF Investments in Skilled Technical Workforce Development
- Final Report Update and Discussion

Plenary Board

Open Session: 11:30–11:50 a.m.

- NSB Chair's Opening Remarks
- Director's Introduction of Dr. Braverman

Task Force on Vision 2030 (Vision TF)

Open Session: 12:45–1:45 p.m.

- Task Force Chair's Opening Remarks
- Update on Vision Project

Plenary Board

Closed Session: 1:25–1:45 p.m.

- NSB Chair's Opening Remarks
- NSF Director's Remarks
  - Science and Security
- Approval of Prior Minutes
- Closed Committee Reports
- Vote: Green Bank Observatory Record of Decision
- Vote: Leadership-Class Computing Facility Operations and Maintenance

Plenary Board (Executive)

Closed Session: 1:45–2:15 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Remarks
  - Executive searches
- Board Member Award Affirmation
- Election of At-large Executive Committee Members

Plenary Board

Open Session: 2:15–2:45 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Remarks
  - Senior Staff Updates
  - Office of Legislative and Public Affairs Item
- Open Committee Chair Reports
- Votes on Merit Review Report Resolution and Preface
- Votes on Semiannual OIG Report and NSF Management Response
- Vote on Executive Committee Annual Report
- NSB Chair's Closing Remarks

Meeting Adjourns: 2:45 p.m.

MEETINGS THAT ARE OPEN TO THE PUBLIC:

Tuesday, May 14, 2019

8:00–8:30 a.m. Plenary NSB
8:30–9:15 a.m. A&F
10:45–11:15 a.m. EE
11:15 a.m.–12:00 p.m. Plenary
1:00–1:45 p.m. Plenary
1:45–3:00 p.m. CS
3:15–3:55 p.m. SEP

Wednesday, May 15, 2019

9:00–10:15 a.m. CO
10:30–11:30 a.m. STW TF
11:30–11:50 a.m. Plenary
12:45–1:25 p.m. Vision TF
2:15–2:45 p.m. Plenary

MEETINGS THAT ARE CLOSED TO THE PUBLIC:

Tuesday, May 14, 2019

9:15–10:30 a.m. A&F

Wednesday, May 15, 2019

1:25–1:45 p.m. Plenary

1:45–2:15 p.m. Plenary Executive

CONTACT PERSONS FOR MORE INFORMATION: The NSB Office contact is Brad Gutierrez, *bgutierr@nsf.gov,* 703–292–7000. The NSB Public Affairs contact is Nadine Lymn, *nlymn@nsf.gov,* 703–292–2490.

SUPPLEMENTARY INFORMATION: Public meetings and public portions of meetings held in the 2nd floor boardroom will be webcast. To view these meetings, go to: *http://www.tvworldwide.com/events/nsf/190514/* and follow the instructions. The public may observe public meetings held in the boardroom. The address is 2415 Eisenhower Avenue, Alexandria, VA 22314.

Please refer to the NSB website for additional information. You will find any updated meeting information and schedule updates (time, place, subject matter, or status of meeting) at *https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

The NSB provides some flexibility around meeting times. After the first meeting of each day, actual meeting start and end times will be allowed to vary by no more than 15 minutes in either direction. As an example, if a 10:00 meeting finishes at 10:45, the meeting scheduled to begin at 11:00 may begin at 10:45 instead. Similarly, the 10:00 meeting may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next meeting would start no later than 11:15. Arrive at the NSB boardroom or check the webcast 15 minutes before the scheduled start time of the meeting you wish to observe.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2019–09765 Filed 5–8–19; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain.*

DATES: Comments regarding this information collection are best assured of having their full effect if received by June 10, 2019.

FOR FURTHER INFORMATION CONTACT: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street NW, Room 10235, Washington, DC 20503, and Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission(s) may be obtained by calling 703–292–7556.

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

Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of 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 should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section.

Title of Collection: Evaluation of the National Science Foundation Advanced Technological Education Program.

OMB Number: 3145–NEW.

Type of Request: Intent to seek approval to establish an information collection.

Abstract: The ATE program is designed to (1) produce more qualified science and engineering technicians to meet workforce demands and (2) improve the technical skills and the general science, technology, engineering, and mathematics (STEM) preparation of these technicians and the educators who teach them. The ATE program provides federal funds through four tracks: Projects, centers, small grants for institutions new to the ATE program, and targeted research on technician education. The purpose of the outcomes study is to examine the capacity of academic institutions to educate STEM technicians, the partnerships between academic institutions and industry, the academic and employment outcomes of students, and the receipt of professional development by technical educators. To that end, the new collection of data for the outcomes study is a web survey of principal investigators (PIs) designed to collect new information about these topics and is scheduled to take place from April 2019 through September 2019. The population of interest consists of projects and centers—the tracks most likely to provide direct support for technician education—that first received funding between fiscal year (FY) 2011 and 2015 and includes awards that are currently active and those that have expired.

Use of the Information: The primary purpose of collecting this information is program evaluation. The data collected will enable NSF to describe program components that are implemented with ATE funds and will be used by NSF to monitor and improve the program and assess its merit and worth. The evaluation will also inform the design of a future impact evaluation.

Expected Respondents: The expected respondents are up to 204 ATE PIs who have received ATE funding since 2007.

Estimate of Burden: The collection occurs once for each respondent. The total estimate for this collection is 204 burden hours and $5,146.

Dated: May 7, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–09675 Filed 5–9–19; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–134 and CP2019–146; MC2019–135 and CP2019–147]

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 a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 14, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
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 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–134 and CP2019–146; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 60 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 6, 2019; *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:* May 14, 2019.

2. *Docket No(s).:* MC2019–135 and CP2019–147; *Filing Title:* USPS Request to Add Priority Mail Contract 527 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 6, 2019; *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:* May 14, 2019.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2019–09671 Filed 5–9–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

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:* May 10, 2019.

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 May 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 60 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–134, CP2019–146.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–09638 Filed 5–9–19; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

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:* May 10, 2019.

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 May 6, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 527 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2019–135, CP2019–147.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–09639 Filed 5–9–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85783; File No. SR–EMERALD–2019–19]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing of a Proposed Rule Change To Amend Exchange Rule 515A Concerning the PRIME Price Improvement and Solicitation Mechanisms and Rules 516 and 517 Regarding Post-Only Orders and Post-Only Quotes

May 6, 2019.

Pursuant to the provisions of 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 April 29, 2019, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing a proposal to amend Exchange Rule 515A, MIAX Emerald Price Improvement Mechanism (''PRIME'') and PRIME Solicitation Mechanism; Rule 516, Order Types Defined; and Rule 517, Quote Types Defined.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald* at MIAX Emerald's principal office, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Exchange Rule 515A, MIAX Emerald Price Improvement Mechanism (''PRIME'') and PRIME Solicitation Mechanism. Specifically, the Exchange proposes to amend the rule to adopt new rule text providing that Post-Only Orders [3] and Post-Only Quotes,[4] collectively referred to as ''Post-Only OQs,'' may participate in a PRIME Auction. Additionally, the Exchange proposes to delete current Interpretation and Policy .07 and adopt new Interpretations and Policies .07 and .08.

PRIME is a process by which a Member [5] may electronically submit for execution (''Auction'') an order it represents as agent (''Agency Order'') against principal interest, and/or an Agency Order against solicited interest.[6] Currently, Post-Only Orders may not participate in a PRIME Auction and are rejected if received while a PRIME Auction is in process.[7] Similarly, the current rule provides that Post-Only Quotes may not participate in a PRIME Auction and are rejected if received during a PRIME Auction.[8] Additionally, if trading interest exists on the MIAX Emerald Book [9] that is subject to the Managed Interest Process pursuant to Exchange Rule 515(c) or there is a Post-Only OQ subject to the POP Process on the MIAX Emerald Book for the option on the same side of the market as the Agency Order, the Agency Order will be rejected by the System [10] prior to initiating an Auction or Solicitation Auction.[11]

The Exchange now proposes to allow Post-Only OQs to participate in a PRIME Auction and to be received during a PRIME Auction as described in more detail below. The Exchange proposes to amend Exchange Rule 516(m), ''Post-Only Orders,'' to remove the sentence that provides that Post-Only Orders may not participate in a PRIME Auction as set forth in Rule 515A(a) and if received during a PRIME Auction will be rejected. The Exchange also proposes to amend Exchange Rule 517(a)(1)(i), ''Post-Only Quotes,'' to remove the sentence that provides that Post-Only Quotes may not participate in a PRIME Auction as set forth in Rule 515A(a) and if received during a PRIME Auction will be rejected. In addition to these proposed changes the Exchange also proposes to amend Rule 515A(a)(1)(iv) which states, ''Post-Only OQs may not participate in PRIME as an Agency Order,[12] principal interest or solicited interest. Post-Only OQs received during a PRIME Auction will be rejected.'' The Exchange proposes to remove the second sentence which states, ''Post-Only OQs received during a PRIME Auction will be rejected.''

The Exchange also proposes to amend subsection (a)(2)(i)(A) to clarify that for both single price submissions and auto-match, if the EBBO [13] on the same side of the market as the Agency Order represents a limit order on the Book or a Post-Only Quote subject to the POP Process,[14] the stop price must be at least $0.01 increment better than the Book price. This proposed change supports the handling of Post-Only OQs in PRIME and clarifies the stop price minimum requirement.

The Exchange proposes to delete current Interpretation and Policy .07 of Rule 515A in its entirety and to adopt new Interpretation and Policy .07 in its stead. New Interpretation and Policy .07 will provide that if trading interest exists on the MIAX Emerald Book that is subject to the POP Process pursuant to Rule 515(i) for the option on the opposite side of the market as the Agency Order, the Agency Order will be automatically executed against the Post-Only interest if the execution would be at a price $0.01 inside the EBBO. For an Agency Order to buy, the price would be $0.01 higher than the EBB, and for an Agency Order to sell the price would be $0.01 lower than the EBO. If the Agency Order is not fully executed after the interest subject to the POP Process is fully exhausted and is no longer at a price equal to the initiating price of the Agency Order, the PRIME Auction will be initiated for the balance of the Agency Order as provided in this Rule. With respect to any portion of an Agency Order that is automatically executed against managed interest pursuant to this paragraph .07, the

[3] *See* Exchange Rule 516(m).

[4] *See* Exchange Rule 517(a)(1)(i).

[5] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[6] *See* Exchange Rule 515A(a).

[7] *See* Exchange Rule 516(m).

[8] *See* Exchange Rule 517(a)(1)(i).

[9] The term ''Book'' means the electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[10] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[11] *See* Exchange Rule 515A(a).07.

[12] *See* Exchange Rule 515A(a).

[13] The term ''EBBO'' means the best bid or offer on the Exchange. *See* Exchange Rule 100.

[14] *See* Exchange Rule 515(i)(3).

exposure requirements contained in Rule 520(b) and (c) will not be satisfied just because the Member utilized the PRIME. The following two examples demonstrate how Post-Only interest resting on the Book is handled.

Example 1. A resting Post-Only OQ subject to the POP Process [15] on the opposite side from the Agency Order causes the Agency Order to automatically execute against the Post-Only interest at a price $0.01 better than the EBBO.

MPV: [16] .05
EBBO: 3.00–3.10 (10x10)
ABBO: [17] 3.00–3.10 (10x10)
Post-Only Order: Sell 1 @3.00

The Exchange receives a Post-Only order to sell at 3.00. Since the Post-Only order is priced equal to the opposite side EBBO it is subject to the POP Process and is therefore booked at 3.05 with a display price of 3.05.

EBBO: 3.00–3.05 (10x1)
PRIME Agency Order: Buy 10 @3.05 [18]

The Exchange then receives a PRIME Agency Order to buy at a price equal to the opposite side EBBO, which includes a Post-Only order subject to the POP Process (without a POP, this would not occur). Since trading interest exists on the MIAX Emerald Book subject to the POP Process on the opposite side of the market from the Agency Order, the Agency Order is automatically executed against the Post-Only interest $0.01 better than the same side EBB.

The PRIME Agency Order to Buy, trades 1 @ 3.01 with the Sell Post-Only order subject to the POP Process.

Since the Agency Order is not fully executed after the Post-Only interest is exhausted, an Auction is initiated for the balance of the order. A Request for Responses (''RFR'') is broadcast to all subscribers detailing the option, side, size and initiating price, and the RFR period is started.[19]

No Responses are received.

The PRIME Auction process will trade the Agency Order with the Contra interest.

The PRIME Agency Order buys 9 from the Contra interest @ 3.05.

Example 2. A resting Post-Only OQ subject to the Managed Interest Process on the opposite side from the Agency Order causes the Agency Order to automatically execute against the Managed Interest at a price equal to or better than the initiating price of the Agency Order.

MPV: .05
EBBO: 2.95–3.10 (10x10)
ABBO: 3.00–3.10 (10x10)

The Exchange receives a Post-Only order to sell at 3.00. Since the Post-Only order is priced equal to the opposite side ABBO, it is subject to the Managed Interest Process and is therefore booked at 3.00 with a display price of 3.05.

EBBO: 2.95–3.05 (10x1)
PRIME Agency Order: Buy 10 @ 3.05

The Exchange then receives a PRIME Agency Order to buy at a price equal to opposite side Post-Only order. Since trading interest exists on the MIAX Emerald Book subject to the Managed Interest Process on the opposite side of the market from the Agency Order, the Agency Order is automatically executed against the Post-Only interest at the resting Managed Interest's Book Price.

The PRIME Agency Order to Buy, trades 1 @ 3.00 with the Sell Post-Only order subject to the Managed Interest Process.

Since the Agency Order is not fully executed after the Post-Only interest is exhausted, an Auction is initiated for the balance of the order. A Request for Responses (''RFR'') is broadcast to all subscribers and the RFR period is started.

No Responses are received.

The PRIME Auction process will trade the Agency Order with the Contra interest.

The PRIME Agency Order buys 9 from the Contra interest @ 3.05.

The Exchange also proposes to adopt new Interpretation and Policy .08 to Rule 515A, to state that if trading interest exists on the MIAX Emerald Book that is subject to the Managed Interest Process pursuant to Rule 515(c) or the POP Process pursuant to Rule 515(i) for the option on the same side of the market as the Agency Order, the Agency Order will be rejected by the System prior to initiating an Auction or Solicitation Auction. The following examples demonstrate this behavior.

Example 3. A resting Post-Only OQ subject to Managed Interest Process on the same side as the Agency Order causes the Agency Order to be rejected.

MPV: .01
EBBO: 1.00–1.06 (10x10)
ABBO: 1.00–1.05 (10x10)
Post-Only Order: Buy 1 @ 1.05

The Exchange receives a Post-Only order to buy at 1.05. Since the Post-Only order is priced equal to the opposite side ABBO, it is subject to the Managed Interest Process and is therefore booked at 1.05 with a display price of 1.04.

EBBO: 1.04–1.06 (10x1)
PRIME Agency Order: Buy 10 @ 1.05

The Exchange then receives a PRIME Agency Order to buy at 1.05 on the same side as the Post-Only order subject to the Managed Interest Process. Since trading interest exists on the MIAX Emerald Book subject to the Managed Interest Process on the same side of the market as the Agency Order, the Agency Order is rejected.

Example 4. A resting Post-Only OQ subject to POP Process on the same side as the Agency Order causes the Agency Order to be rejected.

MPV: .01
EBBO: 1.00–1.05 (10x10)
ABBO: 1.00–1.05 (10x10)
Post-Only Order: Buy 1 @ 1.05

The Exchange receives a Post-Only order to buy at 1.05. Since the Post-Only order is priced equal to the opposite side EBBO it is subject to the POP Process and is therefore booked at 1.04 with a display price of 1.04.

EBBO: 1.04–1.05 (1x10)
PRIME Agency Order: Buy 60 @ 1.05

The Exchange then receives a PRIME Agency Order to buy at 1.05 on the same side as the Post-Only order. Since trading interest exists on the MIAX Emerald Book subject to the POP Process on the same side of the market as the Agency Order, the Agency Order is rejected.

Auction Termination

An Auction shall conclude upon receipt by the System of an unrelated order, including a Post-Only Order, (in the same option as the Agency Order); (i) on the opposite side of the market from the RFR responses, that is marketable against either the NBBO, the initiating price, or the RFR response; or (ii) on the same side of the market as the RFR responses, that is marketable against the NBBO.[20] An Auction will also conclude if the System receives an unrelated limit order, including a Post-Only Order, (in the same option as the Agency Order) on the opposite side of the market from the Agency Order that improves any RFR response.[21] Additionally, an Auction may conclude for any of the other reasons provided for in Rule 515A.[22]

[15] The POP Process is engaged if the limit price of a Post-Only OQ locks or crosses the current side EBBO where the EBBO is the NBBO. *See* Exchange Rule 515(i)(3)(ii).

[16] The term ''MPV'' means minimum price variations. *See* Exchange Rule 510.

[17] The term ''ABBO'' or ''Away Best Bid or Offer'' means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Rule 1400(f)) and calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

[18] The Initiating Member must stop the entire Agency Order as principal or with a solicited order at the better of the NBBO or the Agency Order's limit price (if the order is a limit order). *See* Exchange Rule 515A(a)(1)(ii).

[19] *See* Exchange Rule 515A(a)(2)(i)(B).

[20] *See* Exchange Rule 515A(a)(2)(ii)(B) and (C).

[21] *See* Exchange Rule 515A(a)(2)(ii)(D).

[22] *See* Exchange Rule 515A(a)(2)(ii).

Post-Only Orders and Post-Only Quotes received during a PRIME Auction are treated in similar fashion to other unrelated interest received during a PRIME Auction as described in Rule 515A, however Post-Only Orders and Post-Only Quotes, by definition, will not remove liquidity.[23] If, at the conclusion of a PRIME Auction, same side Post-Only interest remains, the Post-Only interest will be subject to the POP Process as described in Exchange Rule 515(i).

Additionally, the Exchange proposes to amend Interpretation and Policy .12(b) of Rule 515A, which currently describes three scenarios where the System will reject a cPRIME Agency Order at the time of receipt. The Exchange proposes to amend paragraph (b)(iii) which currently provides that a cPRIME Agency Order will be rejected at the time of receipt if any component of the strategy is subject to the Managed Interest Process described in Rule 515(c)(1)(ii). The Exchange proposes to include a reference to Market Maker orders and quotes which may be managed, as described in Rule 515(d); and Post-Only interest being managed under the Post-Only Price Process, as described in Rule 515(i). The Exchange has two separate order management processes for orders; one for non-routable orders, and one specifically for Post-Only Orders (the Post-Only Price Process). Additionally, the Exchange has a management process for Market Maker orders and quotes which operates similarly to the Managed Interest Process.[24] The Exchange proposes to specify that the System will reject a cPRIME Agency Order at the time of receipt if any component of the strategy is subject to the Managed Interest Process described in Rule 515(c)(1), Rule 515(d), or the Post-Only Price Process described in Rule 515(i), to ensure that the integrity of the simple market remains intact. Finally, the Exchange proposes to make a minor non-substantive change to Interpretation and Policy .06 of Rule 515A, to clarify the term ''order'' in the second sentence of the paragraph refers to an Agency Order, and to capitalize the word ''rule'' in the same sentence, to align the text of Interpretation and Policy .06 to the proposed text of Interpretation and Policy .07.

The Exchange also proposes to amend subsection (m) of Exchange Rule 516, Order Types Defined, to delete the statement from the rule text that states, Post-Only Orders may not participate in a PRIME Auction as set forth in Rule 515A(a) and if received during a PRIME Auction will be rejected. Similarly, the Exchange proposes to amend subsection (a)(1)(i) of Exchange Rule 517, Quote Types Defined, to delete the statement from the rule text that states, Post-Only Quotes may not participate in a PRIME Auction as set forth in Rule 515A(a) and if received during a PRIME Auction will be rejected. It is necessary for the Exchange to remove this rule text, as under this proposal Post-Only Orders and Post-Only Quotes may be eligible to participate in a PRIME Auction. Additionally, under this proposal, Post Only Orders and Post-Only Quotes received by the System during a PRIME Auction will not be rejected.

2. Statutory Basis

The Exchange believes that its proposed rule changes are consistent with Section 6(b) of the Act[25] in general, and furthers the objectives of Section 6(b)(5) of the Act[26] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposal to allow Post-Only OQs to participate in a PRIME Auction and to be received during a PRIME Auction promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by increasing the potential liquidity that may be available during a PRIME Auction which may result in possible price improvement opportunities. It is in the investor's best interest to receive the best order execution price.

The proposal to amend Exchange Rule 516(m) and Exchange Rule 517(a)(1)(i) to remove a provision that Post-Only Orders and Post-Only Quotes, respectively, received during a PRIME Auction are rejected, promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by ensuring that the Exchange's rules are accurate and precise concerning the handling of Post-Only Orders and Post-Only Quotes. It is in investors and the public's interest for Exchange rules to be accurate and concise so as to avoid the potential for confusion.

The proposal to amend Rule 515A(a)(2)(ii) to add additional text clarifying the inclusion of Post-Only Orders in certain scenarios that will end a PRIME Auction adds clarity and precision to the Exchange's rule text. It is in investors and the public's interest for Exchange rules to be accurate and concise so as to avoid the potential for confusion.

The proposal to adopt new Interpretation and Policy .07 regarding the System's behavior for trading interest on the Emerald Book subject to the POP Process promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by including resting interest in the PRIME Auction process. Under the Exchange's existing rule the System would reject an Agency Order prior to initiating an Auction if there was resting interest for the option on the same side of the market as the Agency Order. This proposal provides that this interest will now be included in the PRIME Auction which benefits investors and the public interest by including more liquidity in the Auction process and allowing the Auction to occur.

The proposal to adopt new Interpretation and Policy .08 promotes just and equitable principles of trade, removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by providing additional detail regarding trading interest on the MIAX Emerald Book that is subject to the Managed Interest Process or the POP Process. Under the Exchange's existing rule if trading interest existed on the Book that was subject to the Managed Interest Process for the option on the same side of the market as the Agency Order the System would reject the Agency Order prior to initiating an Auction. This behavior remains the same under the Exchange's proposal. Under the Exchange's existing rule if there was a Post-Only OQ on the Book for the option on the same side of the market as the Agency Order the System would reject the Agency Order prior to initiating an Auction. Under the Exchange's proposal, the Exchange has clarified that if there is interest on the Book in the option on the same side of the market as the Agency Order that is

[23] *See* Exchange Rule 516(m) and 517(a)(1)(i) respectively.

[24] *See* Exchange Rule 515(d)(ii).

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

subject to the POP Process pursuant to Rule 515(i) the System will reject the Agency Order prior to initiating an Auction. The Exchange believes this change more accurately describes the behavior of the System in this circumstance and it is in investors and the public's interest for Exchange rules to be accurate and concise so as to avoid the potential for confusion.

The proposal to amend Interpretation and Policy .12 of Exchange Rule 515A, to add additional conditions which will prevent a cPRIME Agency Order from being received promotes just and equitable principles of trade and protects investors and the public interest by ensuring that the integrity of the Simple Market remains intact by rejecting a cPRIME Agency Order if any component of the strategy is subject to a management process or the Post-Only Price Process. The Exchange believes the proposed rule change removes impediments to and perfects the mechanism of a free and open market and a national market system and will result in more efficient trading by ensuring orderly markets involving complex orders with common components. The proposed rule change will protect investors and the public interest by ensuring that executions occurring in a cPRIME auction are valid.

Additionally, the Exchange believes that including additional scenarios which will terminate a cPRIME Auction promotes just and equitable principles of trade and removes impediments to a free and open market by providing greater transparency concerning the operation of Exchange functionality. This provision ensures that a cPRIME Agency Order will always receive the best price on the Exchange while simultaneously preserving the integrity of the simple market.

The proposal to amend Exchange Rule 516 and Rule 517 to remove rule text which states that Post-Only Orders and Post-Only eQuotes, respectively, may not participate in PRIME Auctions and if received during an Auction will be rejected, ensures that the rules of the Exchange accurately describe the Exchange's functionality.

The Exchange believes the proposed changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because they seek to add additional detail to, and improve the accuracy of, the Exchange's rules. In particular, the Exchange believes that the proposed rule changes will provide clarity and transparency of the Exchange's rules to Members and the public, and it is in the public interest for rules to be accurate and concise so as to minimize the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is intended to promote competition by expanding the type of interest that may participate in a PRIME Auction.

The Exchange believes that this enhances intermarket competition by enabling the Exchange to compete for this type of order flow with other exchanges that have similar rules and functionality in place.

The Exchange does not believe the proposal will impose any burden on intra-market competition as the Exchange's rules apply equally to all Members of the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–EMERALD–2019–19 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–EMERALD–2019–19. 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–EMERALD–2019–19 and should be submitted on or before May 31, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–09629 Filed 5–9–19; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85781; File No. SR–FINRA–2019–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change To Expand Time for Non-Parties To Respond to Arbitration Subpoenas and Orders of Appearance of Witnesses or Production of Documents

May 6, 2019.

I. Introduction

On January 29, 2019, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend FINRA Rule 12512(d) through (e) and FINRA Rule 12513(d) through (e) of the Code of Arbitration Procedure for Customer Disputes (''Customer Code'') and FINRA Rule 13512(d) through (e) and FINRA Rule 13513(d) through (e) of the Code of Arbitration Procedure for Industry Disputes (''Industry Code'' and together, ''Codes''), to expand the time for non-parties to respond to arbitration subpoenas and orders of appearance of witnesses or production of documents, and to make related changes to enhance the discovery process for forum users.

The proposed rule change was published for comment in the **Federal Register** on February 12, 2019.[3] The public comment period closed on March 5, 2019. The Commission received four comment letters in response to the Notice, all supporting the proposed rule change.[4] On April 22, 2019, FINRA responded to the comment letters received in response to the Notice.[5] On March 19, 2019, FINRA extended the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to May 13, 2019.[6] This order approves the proposed rule change.

II. Description of the Proposed Rule Change [7]

Parties exchange documents and information to prepare for an arbitration through the discovery process. The Codes currently provide that parties in FINRA arbitration who seek discovery from a non-party may request the panel to issue: (1) An order of appearance of witnesses or production of documents if the non-party is subject to FINRA's jurisdiction as an associated person or member firm or (2) a subpoena if the non-party is not subject to FINRA's jurisdiction.[8] If the panel decides to issue the order or subpoena, FINRA will transmit the signed order or subpoena to the moving party to serve on the non-party.[9] If a non-party receiving an order or a subpoena objects to the scope or propriety of the order or subpoena, the non-party may, within 10 calendar days of service of the order or subpoena, file written objections through the Director of the Office of Dispute Resolution (Director).[10]

FINRA is proposing three amendments to the Codes to enhance the discovery process for forum users, particularly non-parties. Specifically, FINRA is proposing to amend the Codes to:

(1) Extend the response time for non-parties to object to an order or subpoena from 10 calendar days of service to 15 calendar days of receipt of the order or subpoena; [11]

(2) exclude first-class mail as an option to serve documents on a non-party and as an option for the non-party to file the objection to the scope or propriety of the order or subpoena; [12] and

(3) codify the current practice that the Director sends, at the same time, objections and responses to the panel after the reply date has elapsed, unless otherwise directed by the panel.[13]

III. Comment Summary

Supportive Comments

As noted above, the Commission received four comment letters on the proposed rule change.[14] Overall, all four commenters support the proposal and believe that it represents a fair and reasonable approach to helping expedite the arbitration process.[15] More specifically, all four commenters explained that the extension of time to respond to an order or subpoena would help ensure that non-parties have sufficient time to respond to an order or subpoena during arbitration and enhance the discovery process for forum users.[16] The commenters also believe that FINRA's proposed change to the acceptable methods of service would help enable forum users to ''better facilitate and confirm service of subpoenas and orders.'' [17] One

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 85063 (Feb. 6, 2019), 84 FR 3518 (Feb. 12, 2019) (File No. SR–FINRA–2019–004) (''Notice'').

[4] *See* Letter from Steven B. Caruso, Maddox Hargett Caruso, P.C., dated February 11, 2019 (''Caruso Letter''); letter from Christine Lazaro, Public Investors Arbitration Bar Association (''PIABA''), dated February 22, 2019 (''PIABA Letter''); letter from William Jacobson, Cornell Securities Law Clinic, dated March 1, 2019 (''Cornell Letter''); and letter from Nicole Iannarone, Georgia State University College of Law, dated March 5, 2019 (''Georgia State Letter''). Comment letters are available on the Commission's website at *https://www.sec.gov.*

[5] *See* Letter from Kristine A. Vo, Principal Counsel, FINRA, to Ms. Vanessa Countryman, Acting Secretary, U.S. Securities and Exchange Commission, dated April 22, 2019 (''FINRA Letter''). The FINRA Letter is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA, on the Commission's website at *https://www.sec.gov/comments/sr-finra-2019-004/srfinra2019004.htm,* and at the Commission's Public Reference Room.

[6] *See* Letter from Kristine A. Vo, Principal Counsel, FINRA, to Lourdes Gonzalez, Assistant Chief Counsel—Sales Practices, Division of Trading and Markets, Securities and Exchange Commission, dated March 19, 2019.

[7] The subsequent description of the proposed rule change is substantially excerpted from FINRA's description in the Notice. *See* Notice, 84 FR at 3518–3519.

[8] *See* Rules 12512 and 12513. *See also* Rules 13512 and 13513.

[9] *See* Notice, 84 FR at 3518.

[10] *See* Rules 12512 and 12513. *See also* Rules 13512 and 13513.

[11] Receipt of overnight mail service, overnight delivery service, hand delivery, email or facsimile is accomplished on the date of delivery. *See* Notice, 84 FR at 3519, n. 8.

[12] Filing and service by first-class mail is accomplished on the date of mailing, but it can take several days to confirm receipt. For purposes of this rule proposal, service by overnight mail, overnight delivery, hand delivery, facsimile or email is accomplished on the date of delivery.

[13] FINRA states that the Director sends the complete set of motion papers to the panel to ensure that the panel receives the advocacy positions of all parties at the same time.

[14] *See supra* note 4.

[15] *See* Caruso Letter (stating that ''proposed changes would be a fair, equitable and reasonable approach that would expedite and facilitate the efficiency of the arbitration process . . . ''; PIABA Letter (supporting the proposed rule changes ''insofar as they strike a good balance between promoting fast and efficient discovery and allowing for the normal internal operations of third parties to work to respond to subpoenas and orders.''); Georgia State Letter (stating that the proposal would ''promote speed and efficiency in arbitration''); and Cornell Letter (stating that the proposal is an important step towards ''enhancing the discovery process for forum users.'').

[16] *See* Cornell Letter. *See also* Caruso Letter (stating that ''the proposed amendments would address forum users concerns and would help ensure that non-parties wanting to object to an order or subpoena have sufficient time to do so.''); PIABA Letter (supporting ''the proposed rule changes, insofar as they strike a good balance between promoting fast and efficient discovery and allowing for the normal internal operations of third parties to work to respond to subpoenas and orders.''); Georgia State Letter (stating that patterning its rule on those of other fora would create familiarity with the process, resulting in ''more timely answers from non-parties and FINRA spending less time enforcing orders and subpoenas that were not answered.'').

[17] PIABA Letter. *See also* Georgia State Letter (stating that the proposal would ''enhance the speed

Continued

commenter states that the new acceptable service methods would further its efforts to ''provide no-cost advocacy to retail investors who cannot obtain legal representation because [they] do not cost anything.'' [18] This commenter also supports the proposed fifteen-day response deadline because ''it would promote speed and efficiency in arbitration.'' [19]

Additional Guidance

One commenter suggests that FINRA amend the proposal to use service (instead of receipt) as the trigger for determining response deadlines.[20] Specifically, the commenter believes that the use of ''receipt'' instead of ''service'' as a trigger for responses ''introduces uncertainty into the process [because w]hile service can be verified, a serving party may not be aware of when a request is received by a third party.'' [21] The commenter also points out that ''other similar forums currently use service and not receipt as the trigger for calculating a response deadline.'' [22]

In response, FINRA explains that the receipt of overnight mail service, overnight delivery service, hand delivery, email, or facsimile is accomplished on the date of delivery.[23] Accordingly, FINRA believes that parties will be able to determine the date of delivery because, other than for overnight mail service and overnight delivery service, typically delivery will be the same date as service.[24] FINRA also states that the rule change excludes first class mail as an option to serve documents on a non-party, in part, because it may be difficult to determine the date of delivery and, thereby, receipt.[25] For these reasons, FINRA did not take commenter's recommended change.

Similarly, another commenter recommends that FINRA adopt a certified mail option to ''verify when the order or subpoena was received.'' [26] In response, FINRA states that service by overnight mail, overnight delivery, hand delivery, email, or facsimile allow the parties to verify both the date of delivery and receipt and, therefore, certified mail is unnecessary.[27] Accordingly, FINRA did not take the commenters recommended change.

IV. Discussion and Commission Findings

After careful review of the proposed rule change and the comment letters, the Commission finds that the proposal is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.[28] Specifically, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act,[29] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission agrees with FINRA and the commenters that the proposed rule changes would protect investors and the public interest by improving the FINRA arbitration forum for the parties that use it.[30]

As stated in the proposal, forum users have expressed concerns about the amount of time that non-parties have to respond to orders and subpoenas [31] since the individual at a non-party firm who is responsible for responding to an order or subpoena may not actually receive a copy of the order or subpoena until after the tenth day from service has passed.[32] Once the objection to an order or subpoena is waived, the non-party must respond to the order or subpoena or risk incurring sanctions or disciplinary action.[33] Consequently, the Commission believes the extension from 10 calendar days of service to 15 calendar days of receipt of the order or subpoena would address forum users' concerns because the proposal would help to provide sufficient time to non-parties wanting to object to an order or subpoena. Consequently, we also believe that the proposal would also help prevent accidental waivers that could cause sanctions or disciplinary action, protest, and thus further delays in resolving arbitration claims between parties.

The Commission acknowledges one commenter's concern that adopting a trigger for response to a subpoena or order date based on the date of ''receipt'' rather than the date of ''service'' may cause confusion since ''a serving party may not be aware of when a request is received by a third party.'' [34] However, we are also concerned that a non-party to the arbitration may not be able to anticipate the arrival of an order or subpoena, which could lead to inadvertently waiving its right to object. In addition, we note FINRA's statement that parties will be able to determine the date of delivery because, other than for overnight mail service and overnight delivery service, typically delivery will be the same date as service.[35] In sum, the Commission believes that the risks related to the inability to anticipate receipt of a subpoena or order support adopting a trigger date based on the date of receipt rather than the date of service.

The Commission also acknowledges another commenter's request to adopt a certified mail delivery option.[36] However, the Commission also notes that service by overnight mail, overnight delivery, hand delivery, email, or facsimile will allow the parties to verify both the date of delivery and receipt.[37] Therefore, on balance, the Commission believes that the proposed available delivery options will accommodate the commenter's concern.[38]

The Commission also agrees with FINRA's proposal to exclude first-class mail as an option to serve documents on the non-party and as an option for the non-party to file the objection to the scope or propriety of the order or subpoena. As stated in the proposal, forum users have previously raised concerns that the use of first-class mail

of and lower costs in arbitration by amending the methods of service.''); Caruso Letter (stating that the proposal ''enable forum users to be better able to confirm and facilitate the timing of discovery obligations.''); Cornell Letter (predicting that the new proposed service methods would ''speed[] up the time it takes to serve documents to non-parties.'').

[18] Georgia State Letter.

[19] *Id.*

[20] *See id.*

[21] Georgia State Letter.

[22] *Id.* (stating that service is the trigger for responses in federal court, in the JAMS arbitration forum, and to SEC and FTC requests).

[23] *See supra* note 5; *see also* Notice.

[24] *See* FINRA Letter.

[25] *Id.*

[26] *See* Cornell Letter.

[27] *Id.*

[28] In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78*o*–3(b)(6).

[30] *See supra* note 15; *see also* FINRA Letter.

[31] *See* Notice, 84 FR at 3818–3519, n. 4 (citing a letter from Kevin M. Carroll, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Jennifer Piorko Mitchell, Vice President and Deputy Corporate Secretary, FINRA, dated June 2, 2017 (responding to FINRA's March 2017 Special Notice on FINRA's engagement programs), *www.finra.org/sites/default/files/notice_comment_file_ref/SN-32117_SIFMA-KevinCarroll_comment.pdf*).

[32] *See* FINRA Notice at 3519 (Non-parties do not have access to the Dispute Resolution Party Portal (Party Portal). As a result, they are currently served using other means, such as first-class mail, overnight mail service, overnight delivery service, hand delivery, email, or facsimile. Consequently, a firm that is a non-party to an arbitration is not able to anticipate the arrival of an order or subpoena and instruct front-line employees to route these high priority documents to the appropriate individual responsible for responding to the discovery request).

[33] *See* FINRA Notice at 3519 (citing Rules 12212 and 12511). *See also* Rules 13212 and 13511).

[34] Georgia State Letter.

[35] *See* FINRA Letter.

[36] *See* Cornell Letter.

[37] *See* FINRA Letter.

[38] *Id.*

is too slow and thus slows down the discovery process.[39] The Commission agrees that by requiring forum users to serve or transmit discovery-related documents through overnight mail service, overnight delivery, hand delivery, email, or facsimile, the proposal would help forum users confirm and expedite discovery, and therefore expedite the arbitration process.

Finally, the Commission supports the proposal's codification of the current practice that the Director sends, at the same time, objections and responses to the panel after the reply date has elapsed, unless otherwise directed by the panel. This ensures that all members on the panel receive all the parties' advocacy positions at the same time. The Commission agrees that the proposed rule change will enhance forum users' understanding of existing case administration procedures and will improve transparency concerning forum operations.[40]

V. Conclusion

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act[41] that the proposal (SR–FINRA–2019–004), be and hereby is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–09633 Filed 5–9–19; 8:45 am]

BILLING CODE 8011–01–P

[39] *See* FINRA Notice at 3519.

[40] *See* FINRA Notice at 3519 (FINRA notes that the proposed rule change would impact all members, including members that are funding portals or have elected to be treated as capital acquisition brokers (''CABs''), given that the funding portal and CAB rule sets incorporate the impacted FINRA rules by reference).

[41] 15 U.S.C. 78s(b)(2).

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85782; File No. SR–ICEEU–2019–009]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to the ICE Clear Europe Operational Risk Management Policy (''ORM Policy'')

May 6, 2019.

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 May 1, 2019, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes to formalize its Operational Risk Management Policy (''ORM Policy''), which consolidates its practices with respect to management of operational risk. The revisions do not involve any changes to the ICE Clear Europe Clearing Rules or Procedures.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to formalize its ORM Policy which sets out the Clearing House's processes for managing operational risks, the stakeholders responsible for executing those processes, the frequency of review of the policy and the governance and reporting lines for the policy.

The ORM Policy addresses operational risk, which it defines as the risk of an event occurring which negatively impacts the achievement of business objectives resulting from inadequate or failed internal operational controls, people, systems or external events.[4] The ORM Policy establishes an overall process that identifies, assesses, responds to, monitors and reports operational risk.

Risk Identification: Risk identification is performed by the business areas and lines exposed to the risk (referred to as ''risk owners'') at least once each year, and is overseen by the Risk Oversight Department. Risk owners must map their existing processes, linking them to business objectives and identify operational risks where an event might negatively impact the achievement of a business objective. Risk sources must also be identified.

Risk Assessment: Risk assessment is conducted by the risk owners at least once per year in conjunction with risk identification. The potential impact of the risk, including its potential severity and likelihood, are to be evaluated. More frequent ad hoc assessments may be necessary if risks emerge or disappear between annual reviews. For most operational risks, control mechanisms may already exist, in which case uncontrolled and controlled impacts are measured. Risk owners must also assess the sufficiency of existing control mechanisms on a quarterly or, if necessary, a more frequent ad hoc basis.

Risk Response: Risk owners are responsible for proposing and implementing remedial actions, which must be approved by the ICE Clear Europe Executive Risk Committee (the ''ERC''). Depending upon the potential expected impact of the operational risk and the Clearing House risk appetite, the four possible responses to a risk are to treat or mitigate the risk, tolerate or accept the risk, transfer the risk to another party (such as through insurance) or terminate the activity carrying the risk.

Risk Monitoring: Risk owners must monitor the identified operational risk daily through the use of key performance indicators, key risk indicators and other risk indicators such as their own management limits. The Risk Oversight Department itself monitors risks daily through risk appetite metrics and management thresholds as well as operational incidents raised by the risk owners. Risk owners and the Risk Oversight Department also must monitor the performance of control mechanisms on a regular and frequent basis.

Risk Reporting and Oversight: Overall oversight of the policy rests with the Audit Committee and Risk Oversight Department. Specifically, the results of risk assessments must be reported to the Audit Committee and the Board Risk Committee (the ''BRC'') when material changes are observed. Control

[3] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

[4] The ORM Policy notes several non-exhaustive examples of operational risk, including risks from internal and external fraud, employment practices and workplace safety, clients, products and business practices, damage to physical assets and business disruption and system failures.

assessments and operational incidents must be regularly reported to senior management, the Audit Committee and the BRC for appropriate action. The BRC and Board will also be informed of relevant incidents as part of routine reporting. Operational metrics will be provided to the Board and BRC monthly and the ERC daily. The product Risk Committees shall also have access to operational metrics following their schedule of meetings. Unexpected results of operational metrics require escalation and notification to the Board immediately following the event. Identified operational risks must also be compared against established thresholds and reported to the ERC daily and monthly. The ORM Policy itself is subject to review on a biennial basis or in the event of a material change.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments are consistent with the requirements of Section 17A of the Act [5] and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(F) of the Act [6] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. By formalizing ICE Clear Europe's operational risk management and governance process, the amendments are intended to enhance ICE Clear Europe's ability to identify and respond to operational risks presented by its clearing activities. The amendments will thus promote the prompt and accurate clearing of cleared contracts and protects investors and the public interest in the sound operations of the clearing house. Increasing the ability of ICE Clear Europe to identify and respond to operational risks may also enhance the safeguarding of securities and funds in the custody or control of the Clearing House or for which it is responsible, and avoid potential disruption of access to such assets as a result of operational risks. Accordingly, the amendments satisfy the requirements of Section 17A(b)(3)(F).[7]

The policy is also consistent with the requirements of Rule 17Ad–22(e)(17)(i).[8] The ORM Policy is designed to enhance the ability of ICE Clear Europe to identify relevant sources of operational risk, monitor them on an ongoing basis and take appropriate action to respond to such risks. The amendments will therefore facilitate the ongoing identification and mitigation of operational risk, within the meaning of Rule 17Ad–22(e)(17)(i).[9]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments are being adopted to strengthen the Clearing House's internal operational risk management processes and governance and should not affect the rights or obligations of Clearing Members. As a result, ICE Clear Europe does not believe the amendments will affect the cost of clearing for Clearing Members or other market participants, the market for cleared services generally or access to clearing by Clearing Members or other market participants, or otherwise affect competition among Clearing Members or market participants.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2019–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2019–009. 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 such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying

[5] 15 U.S.C. 78q–1.

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 17 CFR 240.17Ad–22(e)(17)(i). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: Manage the covered clearing agency's operational risks by:

(i) Identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls.

[9] 17 CFR 240.17Ad–22(e)(17)(i).

information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2019–009 and should be submitted on or before May 31, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–09632 Filed 5–9–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85788; File No. SR–C2–2019–009]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Opening Process and Add a Global Trading Hours Session for DJX Options

May 6, 2019.

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 April 24, 2019, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') 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 ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') proposes to amend the Exchange's opening process, add a global trading hours session (''Global Trading Hours'' or ''GTH'') for options on the Dow Jones Industrial Average (''DJX options'') and make corresponding changes, update its rule related to trading hours for index options that may be listed for trading on the Exchange, and make other conforming and nonsubstantive changes. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/ctwo/*), 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (''Cboe Global''), which is also the parent company of Cboe Exchange, Inc. (''Cboe Options''), acquired Cboe EDGX Exchange, Inc. (''EDGX''), Cboe EDGA Exchange, Inc. (''EDGA''), Cboe BZX Exchange, Inc. (''BZX or BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with C2, Cboe Options, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). The Cboe Affiliated Exchanges are working to align certain system functionality, retaining only intended differences between the Cboe Affiliated Exchanges, in the context of a technology migration. Cboe Options intends to migrate its technology to the same trading platform used by the Exchange, BZX Options, and EDGX Options in the fourth quarter of 2019. The proposal set forth below is intended to add certain functionality to the Exchange's System that is more similar to functionality offered by Cboe Options in order to ultimately provide a consistent technology offering for market participants who interact with the Cboe Affiliated Exchanges. Although the Exchange intentionally offers certain features that differ from those offered by its affiliates and will continue to do so, the Exchange believes that offering similar functionality to the extent practicable will reduce potential confusion for Users.

Global Trading Hours

The proposed rule change adds a GTH trading session to the Rules. Currently, transactions in equity options (which the proposed rule change clarifies includes options on individual stocks, exchange-traded funds (''Units'' or ''ETFs''), exchange-traded notes (''Index-Linked Exchangeable Notes'' or ''ETNs''), and other securities) may occur from 9:30 a.m. to 4:00 p.m.,[5] except for options on ETFs, ETNs, Index Portfolio Shares, Index Portfolio Receipts, and Trust Issued Receipts the Exchange designates to remain open for trading beyond 4:00 p.m. but no later than 4:15 p.m.[6] Transactions in index options may occur from 9:30 a.m. to 4:15 p.m.[7] As proposed, these hours are referred to as ''Regular Trading Hours.''[8] Regular Trading Hours are consistent with the regular trading hours of most other U.S. options exchanges. Cboe Options has a global trading hours session during which trading in certain option classes, which trading session occurs from 3:00 a.m. to 9:15 a.m.[9] Additionally, many U.S. stock and futures exchanges, which allow for trading in some of their listed products for various periods of time outside of Regular Trading Hours.[10]

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] All times are Eastern time unless otherwise noted.

[6] *See* proposed Rule 6.1(b)(1). The proposed rule changes makes nonsubstantive changes to proposed Rule 6.1(b)(1), including adding defined terms and moving the provision from current paragraph (b) regarding the Exchange's ability to determine that options on individual stocks will trade during different hours under unusual conditions or as otherwise set forth in the Rules to proposed subparagraph (b)(1). The proposed rule change also adds an applicable heading to proposed paragraphs (a) and (d). Additional changes to Rule 6.1 are discussed below.

[7] *See* proposed Rule 6.1(b)(2).

[8] *See also* proposed Rule 1.1, definition of Regular Trading Hours or RTH (the trading session consisting of the regular hours during which transactions in options may be effected on the Exchange, as set forth in Rule 6.1); and Cboe Options Rule 1.1 (definition of Regular Trading Hours).

[9] *See* Cboe Options Rule 6.1.

[10] *See, e.g.,* BZX Rule 1.5(c), (r), (w), and (ee) (regular trading hours from 9:30 a.m. until 4:00 p.m. Eastern time, two early trading sessions (Early Trading Session and Pre-Opening Session) from 7:00 a.m. until 9:30 a.m. and an After Hours Trading Session from 4:00 p.m. to 8:00 p.m. Eastern time); NASDAQ Stock Market LLC Rule 4617 (regular trading hours from 9:30 a.m. until 4:00 p.m. Eastern time and extended trading hours from 4:00 a.m. until 9:30 a.m. and 4:00 p.m. to 8:00 p.m. Eastern time); and New York Stock Exchange LLC Series 900 (providing for an off-hours trading facility to operate outside of the regular 9:30 a.m. to 4:00 p.m. Eastern time trading session); *see also, e.g.,* Chicago Board of Trade Extended Trading Hours for Grain, Oilseeds and Ethanol—Frequently

Continued

As noted above, many U.S. stock exchanges allow for trading in stocks before and after the regular trading hours of 9:30 a.m. to 4:00 p.m., including stocks that comprise the Dow Jones Industrial Average. It is common for investors to engage in hedging and other investment strategies that involve index options and some of the stocks that comprise the underlying index. Currently, this investment activity on the Exchange would be limited to Regular Trading Hours. Additionally, securities trading is a global industry, and investors located outside of the United States generally operate during hours outside of Regular Trading Hours. The Exchange believes there may be global demand from investors for options on DJX, which may be exclusively listed [11] on Cboe Affiliated Exchanges and which the Exchange plans to list during the proposed Global Trading Hours (as defined below), as alternatives for hedging and other investment purposes. Given that DJX options are currently only eligible to trade during Regular Trading Hours, it is difficult for non-U.S. investors to obtain the benefits of trading in this option. It is also difficult for U.S. investors that trade in non-U.S. markets to use these products as part of their global investment strategies. To meet this demand, and to keep pace with the continuing internationalization of securities markets, the Exchange proposes to offer trading in DJX options from 8:30 a.m. to 9:15 a.m. Monday through Friday (''Global Trading Hours'' or ''GTH'').

Proposed Rule 6.1(c) states except under unusual conditions as may be determined by the Exchange, Global Trading Hours are from 8:30 a.m. to 9:15 a.m. on Monday through Friday.[12] While this trading session will be shorter than the global trading hours session on Cboe Options and various stock exchanges, the Exchange believes this proposed trading session will increase the time during which Trading Permit Holders may implement these investment strategies. This GTH trading session will allow market participants to engage in trading these options in conjunction with extended trading hours on U.S. stock exchanges for securities that comprise the index underlying DJX options and in conjunction with part of regular European trading hours. The proposed rule change also adds to Rule 1.1 a definition of trading session, which means the hours during which the Exchange is open for trading for Regular Trading Hours or Global Trading Hours (each of which may be referred to as a trading session), each as defined in proposed Rule 6.1. Unless otherwise specified in the Rules or the context indicates otherwise, all Rules apply in the same manner during each trading session.[13] As discussed below, the Exchange may not permit certain order types or Order Instructions to be applied to orders during Global Trading Hours that it does permit during Regular Trading Hours.

Proposed Rule 6.1(c)(1) provides the Exchange with authority to designate as eligible for trading during Global Trading Hours any exclusively listed index option designated for trading under Cboe Options Rule 24.2.[14] If the Exchange so designates a class, then transactions in options in that class may be made on the Exchange during Global Trading Hours.[15] As indicated above, the Exchange has approved DJX options for trading on the Exchange during Global Trading Hours. The Exchange may list for trading during Global Trading Hours any series in eligible classes that it may list pursuant to Cboe Options Rule 24.9.[16] Any series in eligible classes that are expected to be open for trading during Regular Trading Hours will be open for trading during Global Trading Hours on the same trading day (subject to Rule 6.11 (as proposed to be amended, as discussed below), which sets forth procedures for the opening of trading).[17]

The proposed rule change defines a ''business day'' or ''trading day'' as a day on which the Exchange is open for trading during Regular Trading Hours (this is consistent with the current concept of trading day used but not defined in the Rules).[18] A business day or trading day will include both trading sessions on that day. In other words, if the Exchange is not open for Regular Trading Hours on a day (for example, because it is an Exchange holiday), then it will not be open for Global Trading Hours on that day. Cboe Options has the same definition of business day and trading day.[19]

Global Trading Hours will be a separate trading session from Regular Trading Hours. However, GTH will use the same Exchange servers and hardware as those used during RTH.[20] All Trading Permit Holders may participate in Global Trading Hours. Trading Permit Holders do not need to apply or take any additional steps to participate in Global Trading Hours. Additionally, because the Exchange will use the same servers and hardware during Global Trading Hours as it uses for Regular Trading Hours, Trading Permit Holders may use the same ports and connections to the Exchange for all trading sessions.[21] The Book used during Regular Trading Hours will be the same Book used during Global Trading Hours.[22]

Asked Questions (indicating that certain agricultural commodity products are available for electronic trading 21 hours a day on the CME Globex trading platform); and Intercontinental Exchange, Inc. Regular Trading & Support Hours (indicating that many of its listed products are available for trading for periods of time outside of Regular Trading Hours, including overnight sessions).

[11] An ''exclusively listed option'' is an option that trades exclusively on an exchange (or exchange group) because the exchange has an exclusive license to list and trade the option or has the proprietary rights in the interest underlying the option. An exclusively listed option is different than a ''singly listed option,'' which is an option that is not an ''exclusively listed option'' but that is listed by one exchange and not by any other national securities.

[12] *See also* proposed Rule 1.1, definition of Global Trading Hours or GTH (the trading session consisting of the hours outside of Regular Trading Hours during which transactions in options may be effected on the Exchange and are set forth in Rule 6.1); and Cboe Options Rule 1.1 (definition of Global Trading Hours).

[13] This includes business conduct rules in Chapter 4 and rules related to doing business with the public in Chapter 9. Additionally a broker-dealer's due diligence and best execution obligations apply during Global Trading Hours. *See also* Cboe Options Rule 6.1A(a).

[14] Chapter 24 incorporates by reference Cboe Options Rule 24.2 into the Exchange's rules. A class that the Exchange lists for trading during RTH only will be referred to as an ''RTH class,'' and a class the Exchange lists for trading during both GTH and RTH will be referred to as an ''All Sessions class.'' *See* Rule 1.1, proposed definitions of ''All Sessions classes'' and ''RTH classes.''

[15] The Exchange believes it is appropriate to retain flexibility to determine whether to operate during Global Trading Hours so that it can complete all system work on other preparations prior to implementing Global Trading Hours in a class, and so that the Exchange can evaluate trading activity during Global Trading Hours once implemented and determine whether to continue or modify the trading session (subject to applicable rule filings).

[16] Chapter 24 incorporates by reference Cboe Options Rule 24.9 into the Exchange's rules. *See also* Cboe Options Rule 6.1A(c).

[17] *See also* Cboe Options Rule 6.1A(c).

[18] The proposed rule change makes corresponding changes to the definitions of market open and market close in Rule 1.1 to provide that each term specifies the start or end, respectively, of a trading session.

[19] *See* Cboe Options Rule 1.1.

[20] This is different than the trading sessions on Cboe Options, which uses different servers and hardware for each trading session.

[21] Only Trading Permit Holders will be able to access the System during any trading session. Cboe Options Trading Permit Holders must obtain a separate permit and use different connections to participate in global trading hours. *See* Cboe Options Rules 3.1 and 6.1A(d).

[22] *See* proposed Rule 1.1, which amends the definition of Book to mean the electronic book of simple orders and quotes maintained by the System on which orders and quotes may execute during the applicable trading session. The Book during GTH may be referred to as the ''GTH Book,'' and the Book during RTH may be referred to as the ''RTH Book.'' The additional language regarding the

As further discussed below, the Exchange expects there to be reduced liquidity, higher volatility, and wider markets during Global Trading Hours, and investors may not want their orders or quotes to execute during Global Trading Hours given those trading conditions. To provide investors with flexibility to have their orders and quotes execute only during RTH, or both RTH and GTH, the proposed rule change adds an All Sessions order and an RTH Only order. An ''All Sessions'' order is an order a User designates as eligible to trade during both GTH and RTH. An unexecuted All Sessions order on the GTH Book at the end of a GTH trading session enters the RTH Queuing Book and becomes eligible for execution during the RTH opening rotation and trading session on the same trading day, subject to a User's instructions (for example, a User may cancel the order).[23] An ''RTH Only'' order is an order a User designates as eligible to trade only during RTH or not designated as All Sessions. An unexecuted RTH Only order with a Time-in-Force of GTC or GTD on the RTH Book at the end of an RTH trading session enters the RTH Queuing Book and becomes eligible for execution during the RTH opening rotation and trading session on the following trading day (but not during the GTH trading session on the following trading day), subject to a User's instructions.[24]

Because trading sessions are completely separate on Cboe Options, there are not distinct order types corresponding to the proposed RTH Only and All Sessions order instructions. An order or quote submitted to GTH on Cboe Options may only execute during GTH, and an order or quote submitted to RTH on Cboe Options may only execute during RTH. The proposed RTH Only order is equivalent to any order submitted to RTH on Cboe Options. While the Exchange is not proposing an equivalent to an order submitted to GTH on Cboe Options, and instead is proposing an All Sessions order, Users may still submit an equivalent to a ''GTH only'' order by submitting an All Sessions order with a good-til-date Time-in-Force, with a time to cancel before the RTH market open. Therefore, Users can submit orders to participate in either trading session, or both, and thus the proposed rule change provides Users with additional flexibility and control regarding in which trading sessions their orders and quotes may be eligible to trade.

Generally, trading during the GTH trading session will occur in the same manner as it occurs during the RTH trading session. However, because the GTH market may have different characteristics than the RTH market (such as lower trading levels, reduced liquidity, and fewer participants), the Exchange may deem it appropriate to make different determinations for trading rules for each trading session. Proposed Rule 1.2(b) states to the extent the Rules allow the Exchange to make a determination, including on a class-by-class or series-by-series basis, the Exchange may make a determination for GTH that differs from the determination it makes for RTH.[25] The Exchange maintains flexibility with respect to certain rules so that it may apply different settings and parameters to address the specific characteristics of that class and its market. For example, Rule 6.12(a)(2) allows the Exchange to determine electronic allocation algorithms on a class-by-class basis;[26] and Rule 6.10(a) allows the Exchange to make certain order types, Order Instructions, and Times-in-Force not available for all Exchange systems or classes (and unless stated in the Rules or the context indicates otherwise, as proposed).[27] Because trading characteristics during RTH may be different than those during GTH (such as lower trading levels, reduced liquidity, and fewer participants), the Exchange believes it is appropriate to extend this flexibility to each trading session. The Exchange represents that it will have appropriate personnel available during GTH to make any determinations that Rules provide the Exchange or Exchange personnel will make (such as trading halts, opening series, and obvious errors).

The proposed rule change amends Rule 8.2(a) to provide that a Market-Maker's selected class appointment applies to classes during all trading sessions. In order words, if a Market-Maker selects an appointment in DJX options, that appointment would apply during both GTH and RTH (and thus, the Market-Maker would have an appointment to make markets in DJX during both GTH and RTH). As a result, a Market-Maker continuous quoting obligations set forth in Rule 8.6(d) would apply to the class for an entire trading day (including both trading sessions), which is comprised of 7.5 hours.[28] Pursuant to Rule 8.6(d), a Market-Maker must enter continuous bids and offers in 60% of the cumulative number of seconds, or such higher percentage as the Exchange may announce in advance, for which that Market-Maker's appointed classes are open for trading, excluding any adjusted series, any intra-day add-on series on the day during which such series are added for trading, any Quarterly Option Series, and any series with an expiration of greater than 270 days. The Exchange calculates this requirement by taking the total number of seconds the Market-Maker disseminates quotes in each appointed class (excluding the series noted above), and dividing that time by the eligible total number of seconds each appointed class is open for trading that day.[29] As proposed, the 45 minutes that comprise Global Trading Hours during which the Exchange will list series of DJX options[30] will be included in the denominator of this calculation. The Exchange expects to list 720 series of DJX options, 300 of which with expirations of greater than 270 days. Therefore, 420 series will be counted for purposes of determining a Market-Maker's continuous quoting obligation for the number of minutes the series are open during Global Trading Hours.

For example, suppose a Market-Maker has appointments in ten classes. Assume there are 2,000 series

execution of orders and quotes is intended to distinguish the Book from the Queuing Book, on which orders and quotes may not execute, as discussed below. With respect to complex orders, the same complex order book (''COB'') will be used for all trading sessions. *See* proposed Rule 6.13(a) (definition of COB). This is different than Cboe Options, which uses separate books for each trading session, which are not connected.

[23] *See* Rule 6.10, proposed definition of All Sessions order.

[24] *See* Rule 6.10, proposed definition of RTH Only order. The RTH Only and All Sessions order instructions will also be available for complex orders. *See* proposed Rule 6.13(b).

[25] The proposed rule change modifies paragraph numbering and lettering in current Rule 1.2, and provides that Exchange determinations may be provided for in the Rules, in addition to specifications, Notices, and Regulatory Circulars.

[26] Therefore, the allocation algorithm that applies to a class during RTH may differ from the allocation algorithm that apply to that class during GTH.

[27] The proposed rule change amends Rule 6.10(a) to explicitly state that the Exchange may make these determinations on a trading session basis. The proposed rule change also clarifies in the Rules that Rule 6.13 sets forth the order types, Order Instructions, and Times-in-Force the Exchange may make available for complex orders.

[28] *See* proposed Rule 8.6(d). The appointment cost in Rule 8.3 will apply to a class for all trading sessions. Therefore, to have an appointment during GTH, a Market-Maker will not have to select a separate appointment or obtain a new Trading Permit to be able to quote in a class during GTH. This is different from Cboe Options, which applies Market-Maker appointments separately to each trading session. *See* Cboe Options Rules 6.1A(e) and 8.7(d).

[29] The proposed rule change clarifies that the time the Exchange is open for trading on a trading day (including all trading sessions) will be considered when determining a Market-Maker's satisfaction of this obligation.

[30] This is the number of DJX series currently listed on Cboe Options.

(excluding series with quarterly expirations and expirations of greater than 270 days) in each class, for a total of 20,000 series, and all series in each of those ten classes are open for trading from 9:30:30 to 4:00:00. That would create an eligible total number of seconds for each series of 23,370 seconds (and thus, a total of 467,400,000 seconds for all appointed classes in the aggregate) each trading day. To satisfy its continuous quoting obligation, the Market-Maker would need to be quoting for 60% of that time in any combination of series across those classes (or a total of at least 280,440,000 seconds). Suppose when the Exchange begins listing DJX options on the Exchange for both GTH and RTH, the Market-Maker selects a DJX appointment, and the Exchange lists 420 series of DJX options that do not have quarterly expirations or expirations of greater than 270 days. Assume all series in DJX are open for trading from 8:30:30 to 9:15:00 and 9:30:30 to 4:15:00. That would create an eligible total number of seconds of 1,121,400 seconds during GTH and 10,193,400 seconds during RTH, for a total of 11,314,800 seconds, for DJX during the trading day). If DJX were only listed during RTH, the total eligible quoting time would be 477,593,400 seconds across the eleven classes, and a Market-Maker would be required to quote 286,556,040 seconds in series across those classes. If DJX were listed in both RTH and GTH, the total eligible quoting time would be 478,714,000 seconds during a trading day across all eleven classes, and the Market-Maker would be required to quote 287,228,880 seconds across series in the eleven classes. Therefore, extending the DJX continuous quoting obligation for a Market-Maker with appointments in a total of eleven classes, including DJX, would increase a Market-Maker's required quoting time by 672,840 seconds, or 0.23%. The Market-Maker could determine to satisfy this increase during RTH or GTH in any of its appointed classes. For example, if a Market-Maker selects a DJX appointment but does not want to participate during GTH, the Market-Maker could add this quoting time during RTH (*e.g.,* given the total of 20,420 series across its 11 appointed classes, the Market-Maker could quote an additional 67.25 seconds (just over 1 minute) in each of 10,000 of those series (fewer than half of its appointed series) on a trading day, it could satisfy its continuous quoting obligation without quoting in any DJX series during any portion of GTH.

As the above example demonstrates, while the proposed rule change will increase the total time during which a Market-Maker with a DJX appointment must quote, this increase is de minimis given that a Market-Maker's compliance with its continuous quoting obligation is based on all classes in which it has an appointment in the aggregate. Selecting an appointment in DJX options will be optional and within the discretion of a Market-Maker. Additionally, the Exchange is providing Market-Makers with the opportunity to quote during GTH (and receive the benefits of acting as a Market-Maker with respect to transactions it effects during that time) without obtaining an additional Trading Permit or creating additional connections to the Exchange (as is required on Cboe Options). Given this ease of access to the GTH trading session, the Exchange believes Market-Makers may be encouraged to quote during that trading session. The Exchange believes Market-Makers will have an incentive to quote in DJX options during Global Trading Hours given the significance of the Dow Jones Industrial Average within the financial markets, the expected demand, and given that the stocks underlying the index are also trading during those hours (which may permit execution of certain hedging strategies). Extending a Market-Maker's appointment to Global Trading Hours will enhance liquidity during that trading session, which benefits all investors during those hours. Therefore, the Exchange believes the proposed rule change provides customer trading interest with a net benefit, and continues to maintain a balance of Market-Maker benefits and obligations.

The proposed rule change amends the definitions of market orders, stop (stop-loss) orders, and stop-limit orders to state that those order types and order instructions may not be applied to orders designated as All Sessions order (*i.e.,* market orders, stop, and stop-limit orders will not be eligible for trading during GTH).[31] The Exchange expects reduced liquidity, higher volatility, and wider spreads during GTH. Therefore, the Exchange believes it is appropriate to not allow these orders to participate in GTH trading in order to protect customers should wide price fluctuations occur due to the potential illiquid and volatile nature of the market or other factors that could impact market activity.[32]

Proposed Rule 6.1(c)(3) provides that no current index value underlying an index option trading during Global Trading Hours will be disseminated during or at the close of that trading session. The value of the underlying index will not be recalculated during or at the close of Global Trading Hours. The closing value of the index from the previous trading day will be available for Trading Permit Holders that trade during Global Trading Hours. However, the Exchange does not believe it would be useful or efficient to disseminate to Trading Permit Holders the same value repeatedly at frequent intervals, as it does during Regular Trading Hours (when that index value is being updated).[33]

Proposed Rule 3.19 requires Trading Permit Holders to make certain disclosures to customers regarding material trading risks that exist during Global Trading Hours. The Exchange expects overall lower levels of trading during Global Trading Hours compared to Regular Trading Hours. While trading processes during Global Trading Hours will be substantially similar to trading processes during Regular Trading Hours (as noted above), the Exchange believes it is important for investors, particularly public customers, to be aware of any differences and risks that may result from lower trading levels and thus requires these disclosures. Proposed Rule 3.19 provides that no Trading Permit Holder may accept an order from a customer for execution during Global Trading Hours without disclosing to that customer that trading during Global Trading Hours involves material trading risks, including the possibility of lower liquidity (including fewer Market-Makers quoting), higher volatility, changing prices, an exaggerated effect

[31] The proposed rule change also amends the introductory language to Rule 6.10(c) to provide that certain restrictions on the use of Order Instructions may be set forth in the Rules (such as the proposed restrictions on the use of market orders, stop orders, and stop-limit orders during GTH).

[32] Cboe Options Rule 6.1A(f) also prohibits these orders from participating in GTH trading. Cboe Options Rule 6.1A(f) also prohibits good-til-cancelled orders from participating during GTH. However, because the Exchange will use the same Book for all trading sessions, and thus any GTC orders that do not trade during GTH may become eligible for trading during RTH, the Exchange does not believe it is necessary to restrict use of this time-in-force.

[33] Cboe Options Rules 24.2(b)(10), (d)(8), (e)(7), and (f)(11) (which are incorporated by reference into the Exchange's Rules pursuant to Chapter 24) provide that underlying index values will be disseminated at least once every 15 seconds. Proposed Rule 6.1(c)(3) supersedes those provisions with respect to Global Trading Hours. Cboe Options Rule 24.3 also states that dissemination of the current index value will occur after the close of Regular Trading Hours (and, thus, not after the close of Global Trading Hours, as no new index value will have been calculated during that trading session) and from time-to-time on days on which transactions are made on the Exchange.

from news announcements, wider spreads, the absence of an updated underlying index or portfolio value or intraday indicative value and lack of regular trading in the securities underlying the index or portfolio and any other relevant risk. The proposed rule provides an example of these disclosures. The Exchange believes that requirement Trading Permit Holders to disclose these risks to non-TPH customers will facilitate informed participation in Global Trading Hours.

The Exchange also intends to distribute to Trading Permit Holders and make available on its website a Regulatory Circular regarding Global Trading Hours that discloses, among other things, that (1) the current underlying index value may not be updated during Global Trading Hours, (2) that lower liquidity during Global Trading Hours may impact pricing, (3) that higher volatility during Global Trading Hours may occur, (4) that wider spreads may occur during Global Trading Hours, (5) the circumstances that may trigger trading halts during Global Trading Hours, (6) required customer disclosures (as described above), and (7) suitability requirements. The Exchange believes that, with this disclosure, Global Trading Hours are appropriate and beneficial notwithstanding the absence of a disseminated updated index value during those hours.

As set forth above, the differences in the Rules between the trading process during RTH and during GTH is that certain order types and instructions will not be available during GTH, no values for indexes underlying index options will be disseminated during GTH, and Trading Permit Holders that accept orders from customers during GTH will be required to make certain disclosures to those customers. As noted above, other rules will apply in the same manner, but the Exchange may make different determinations between RTH and GTH. The Exchange believes these differences are consistent with the differences between the characteristics of each trading session. The Exchange also notes the following:

- All Trading Permit Holders may, but will not be required to, participate during Global Trading Hours. As noted above, while a Market-Maker's appointment to an All Sessions class will apply to that class whether it quotes in series in that class or not during GTH, the Exchange believes any additional burden related to the application of a Market-Maker's quoting obligation to the additional 45 minutes will be de minimis. The Exchange believes even if a Market-Maker elects to not quote during GTH, its ability to satisfy its continuous quoting obligation will not be substantially obligated given the short length of GTH and the few series that will be listed for trading during GTH.
- The Exchange expects Trading Permit Holders that want trading during GTH to have minimal preparation. The Exchange will use the same connection lines, message formats, and feeds during RTH and GTH.[34] Trading Permit Holders may use the same ports and EFIDs for each trading session.[35]
- The same opening process (as amended below) will be used to open each trading session.
- Order processing will operate in the same manner during Global Trading Hours as it does during Regular Trading Hours. There will be no changes to the ranking, display, or allocation algorithms rules (as noted above, the Exchange will have authority to apply a different allocation algorithm to a class during Global Trading Hours than it applies to that class during Regular Trading Hours).
- There will be no changes to the processes for clearing, settlement, exercise, and expiration.[36]
- The Exchange will report the Exchange best bid and offer and executed trades to the Options Price Reporting Authority (''OPRA'') during Global Trading Hours in the same manner they are reported during Regular Trading Hours. Exchange proprietary data feeds will also be disseminated during Global Trading Hours using the same formats and delivery mechanisms with which the Exchange disseminates them during Regular Trading Hours. Use of these proprietary data wills during Global Trading Hours will be optional (as they are during Regular Trading Hours).[37]
- The same Trading Permit Holders that are required to maintain connectivity to a backup trading facility during Regular Trading Hours will be required to do so during Global Trading Hours.[38] Because the same connections and serves will be used for both trading sessions, a Trading Permit Holder will not be required to take any additional action to comply with this requirement, regardless of whether the Trading Permit Holder chooses to trade during Global Trading Hours.
- The Exchange will process all clearly erroneous trade breaks during Global Trading Hours in the same manner it does during Regular Trading Hours and will have Exchange officials available to do so (the same officials that do so during Regular Trading Hours).
- The Exchange will perform all necessary surveillance coverage during Global Trading Hours.
- The Exchange may halt trading during Global Trading Hours in the interests of a fair and orderly market in the same manner it may during Regular Trading Hours pursuant to Rule 6.32 (as proposed to be amended, as described below). The proposed rule change amends Rule 6.32(a) to provide that when the hours of trading of the underlying primary securities market for an index option do not overlap or coincide with those of the Exchange, and during Global Trading Hours, Rule 6.32(a)(1) and (2) (as proposed) do not apply. As discussed above, Global Trading Hours will not coincide with the hours of trading of the underlying primary securities market. Generally, the Exchange considers halting trading only in response to unusual conditions or circumstances, as it wants to interrupt trading as infrequently as possible and only if necessary to maintain a fair and orderly market. During Regular Trading Hours, it would be unusual, for example, for stocks or options underlying an index to not be trading or the current calculation of the index to not be available. However, as discussed above, there will be no calculation of underlying indexes during Global Trading Hours, and Global Trading Hours do not coincide with the regular trading hours of the

[34] The same telecommunications lines used by Trading Permit Holders during Regular Trading Hours may be used during Global Trading Hours, and these lines will be connected to the same application serve at the Exchange during both trading sessions. This is different from Cboe Options, which connects its telecommunications lines to a separate application serve during each trading session.

[35] A Trading Permit Holder may elect to have separate ports or EFID for each trading session, but the Exchange will not require that. This is different from Cboe Options, which requires Trading Permit Holders to use separate log-ins and acronyms (the equivalent of ports and EFIDs) for each trading session.

[36] The Exchange has held discussions with the Options Clearing Corporation, which is responsible for clearance and settlement of all listed options transactions and has informed the Exchange that it will be able to clear and settle all transactions that occur on the Exchange and handle exercises of options during Extended Trading Hours.

[37] Any fees related to receipt of the OPRA data feed during Global Trading Hours will be included on the OPRA fee schedule. Any fees related to receipt of the Exchange's proprietary data feeds during Global Trading Hours will be included on the Exchange's fee schedule (and will be included in a separate rule filing) or the Exchange's market data website, as applicable.

[38] Currently, Trading Permit Holders with accounts for 5% or more of the executed volume, measured on a quarterly basis, the Exchange must connect to the Exchange's backup facilities and participate in testing. The same test will be used for all trading sessions. *See* C2 Options Regulatory Circular 18–011 (July 3, 2018); and Rule 6.34.

underlying stock or options (there may be some overlap with trading of certain underlying stocks, as mentioned above [39]). Thus, the factors described in Rule 6.32(a) (as proposed to be amended) are not unusual for Global Trading Hours, and thus the Exchange does not believe it is necessary to consider these as reasons for halting trading during that trading session. Exclusion of Global Trading Hours from those provisions will allow trading during that trading session to occur despite the existence of those conditions (if the Exchange considered the existence of those conditions during Global Trading Hours, trading during Global Trading Hours could be halted every day). It is appropriate for the Exchange to consider any unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market during Global Trading Hours, which may, for example, include whether the underlying primary securities market was halted at the close of the previous trading day (in which case the Exchange will evaluate whether the condition that led to the halt has been resolved or would not impact trading during Global Trading Hours) or significant events that occur during Global Trading Hours.

Pursuant to Interpretation and Policy .01, the Exchange will halt trading in all options when a market-wide trading halt known as a circuit breaker is initiated in response to extraordinary market conditions. Pursuant to the proposed rule change, Interpretation and Policy .01 will not apply during Global Trading Hours. The Exchange believes that, even if stock trading was halted at the close of the previous trading day, the length of time between that time and the beginning of Global Trading Hours is significant (over 16 hours), and the condition that led to the halt is likely to have been resolved. The proposed rule change allows the Exchange to consider unusual conditions or circumstances when determining whether to halt trading during Global Trading Hours. To the extent a circuit breaker caused a stock market to be closed at the end of the prior trading day, the Exchange could consider, for example, whether it received notice from stock exchanges that trading was expected to resume (or not) the next trading day in determining whether to halt trading during Global Trading Hours. Because the stock markets would not begin trading until after Global Trading Hours opens, the Exchange believes it should be able to open Global Trading Hours rather than waiting to see whether stock markets open to allow investors to participate in Global Trading Hours if the Exchange believes such trading can occur in a fair and orderly manner based on then-existing circumstances, not circumstances that existed numerous hours earlier. Additionally, Cboe Options has the same rule provision.[40]

Certain rules currently include general phrases related to a day or trading, such as market close. The proposed rule change makes technical changes to Rules 6.9(e),[41] 6.10(d) (definition of ''Day''), and 6.13(c) and (i) to incorporate the terminology included in this proposed rule change to specify the appropriate trading session(s) being referenced in those rules.

The Exchange will disseminate last sale and quotation information during Global Trading Hours through OPRA pursuant to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (the ''OPRA Plan''), as it does during Regular Trading Hours.[42] The Exchange will also disseminate an opening quote and trade price through OPRA for Global Trading Hours (as it does for Regular Trading Hours). Therefore, all Trading Permit Holders that trade during Global Trading Hours will have access to quote and last sale information during that trading session.

The Exchange understands that systems and other issues may arise and is committed to resolving those issues as quickly as possible, including during Global Trading Hours. Thus, the Exchange will have appropriate staff on-site and otherwise available as necessary during Global Trading Hours to handle any technical and support issues that may arise during those hours. Additionally, the Exchange will have personnel available to address any trading issues that may arise during Global Trading Hours.[43] The Exchange is also committee to fulfilling its obligations as a self-regulatory organization at all times, including during Global Trading Hours, and will have appropriately trained, qualified regulatory staff in place during Global Trading Hours to the extent it deems necessary to satisfy those obligations. The Exchange's surveillance procedures will be revised as necessary to incorporate transactions that occur and orders and quotations that are submitted during Global Trading Hours. The Exchange believes its surveillance procedures are adequate to properly monitor trading of DJX options during Global Trading Hours.

Opening Process

Rule 6.11 sets forth the opening process the Exchange uses to open series on the Exchange at the market open each trading day (and after trading halts). Pursuant to the current opening process, the System determines and opening price for a series based on the NBBO [44] and crosses any interest on the book that is marketable at that price. The proposed rule change adopts an opening auction process, substantially similar to the Cboe Options opening auction process.[45] The Exchange believes an opening auction process will enhance the openings of series on the Exchange by providing an opportunity for price discovery based on then-current market conditions. Pursuant to the proposed opening auction process, the Exchange will have a Queuing Period, during which the System will accept orders and quotes and disseminates expected opening information; will initiate an opening rotation upon the occurrence of certain triggers; will conduct an opening rotation during which the System matches and executes orders and quotes against each other in order to establish an opening Exchange best bid and offer and trade price, if any, for each series,

[39] *See supra* note 10.

[40] *See* Cboe Options Rule 24.7(d).

[41] The proposed rule change makes an additional nonsubtantive change to Rule 6.9, as well as modifies the name of Rule 6.9 to account for the fact that Rule 6.9 applies to the cancellation, as well as the entry, of orders.

[42] The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are trading on the participant exchanges. The OPRA Plan is a national market system plan approved by the Commission pursuant to Section 11A of the Act and Rule 608 thereunder. *See* Securities Exchange Act Release No. 17638 (March 18, 1981). The full text of the OPRA Plan is available at *http://www.opradata.com.* All operating U.S. options exchanges participate in the OPRA Plan. The operator of OPRA informed the Exchange that it intends to add a modifier to the information disseminated during Global Trading Hours (as it does for Cboe Options).

[43] The Exchange notes that, to conduct trading during global Trading Hours, persons that are not Trading Permit Holders, such as employees of affiliates of Trading Permit Holders located outside of the United States, may be transmitting orders and quotes during Global Trading Hours (such non-Trading Permit Holders would not have direct access to the Exchange, and thus those orders and quotes would be submitted to the Exchange through Trading Permit Holders' systems subject to applicable laws, rule, and regulations). Trading Permit Holders may authorize (in a form and manner determined by the Exchange) individuals at these non-Trading Permit Holder entities to contact the Exchange during Global Trading Hours to address any issues.

[44] The opening price (if not outside the NBBO and no more than a specified minimum amount away from the NBBO) is either the midpoint of the NBBO, the last disseminated transaction price after 9:30 a.m., or the last transaction price from the previous trading day. *See* current Rule 6.11(a)(2) and (3).

[45] *See* Cboe Options Rule 6.2.

subject to certain price protections; and will open series for trading.[46]

Proposed Rule 6.11(a) sets forth the definitions of the following terms for purposes of the opening auction process in proposed Rule 6.11:[47]

• *Composite Market:* The term ''Composite Market'' means the market for a series comprised of (1) the higher of the then-current best appointed Market-Maker bulk message bid on the Queuing Book and the away best bid (''ABB'') (if there is an ABB) and (2) the lower of the then-current best appointed Market-Maker bulk message offer on the Queuing Book and the away best offer (''ABO'') (if there is an ABO). The term ''Composite Bid (Offer)'' means the bid (offer) used to determine the Composite Market.[48]

• *Composite Width:* The term ''Composite Width'' means the width of the Composite Market (*i.e.,* the width between the Composite Bid and the Composite Offer) of a series.

• *Maximum Composite Width:* The term ''Maximum Composite Width'' means the amount that the Composite Width of a series may generally not be greater than for the series to open (subject to certain exceptions, as described below). The Exchange determines this amount on a class and Composite Bid basis, which amount the Exchange may modify during the opening auction process (which modifications the Exchange disseminates to all subscribers to the Exchange's data feeds that deliver opening auction updates).[49]

• *Opening Auction Updates:* The term ''opening auction updates'' means Exchange-disseminated messages that contain information regarding the expected opening of a series based on orders and quotes in the Queuing Book for the applicable trading session and, if applicable, the GTH Book,[50] including the expected opening price, the then-current cumulative size on each side at or more aggressive than the expected opening price, and whether the series would open (and any reason why a series would not open).

• *Opening Collar:* The term ''Opening Collar'' means the price range that establishes limits at or inside of which the System determines the Opening Trade Price for a series. The Exchange determines the width of this price range on a class and Composite Bid basis, which range the Exchange may modify during the opening auction process (which modifications the Exchange disseminates to all subscribers to the Exchange's data feeds that deliver opening auction updates.[51]

• *Opening Trade Price:* The term ''Opening Trade Price'' means the price at which the System executes opening trades in a series during the opening rotation.[52]

• *Queuing Book:* The term ''Queuing Book'' means the book into which Users may submit orders and quotes (and onto which GTC and GTD orders remaining on the Book from the previous trading session or trading day, as applicable, are entered) during the Queuing Period for participation in the application opening rotation.[53] Orders and quotes on the Queuing Book may not execute until the opening rotation. The Queuing Book for the GTH opening auction process may be referred to as the ''GTH Queuing Book,'' and the Queuing Book for the RTH opening auction process may be referred to as the ''RTH Queuing Book.''

• *Queuing Period:* The term ''Queueing Period'' means the time period prior to the initiation of an opening rotation during which the System accepts orders and quotes for participation in the opening rotation for the applicable trading session.[54]

Proposed paragraph (b) describes the Queuing Period. The Queuing Period begins at 7:30 a.m. for all class.[55] This is the same time at which the System begins accepting orders and quotes today. Therefore, Users will have the same amount of time to submit orders and quotes prior to the RTH opening. Additionally, Users will have one hour to submit orders and quotes in GTH classes prior to the GTH opening. The Exchange believes this is sufficient given that the Exchange will list fewer classes (one class, as proposed) during GTH.[56]

Proposed subparagraph (b)(2) clarifies that orders and quotes on the Queuing Book are not eligible for execution until the opening rotation pursuant to proposed paragraph (e), as described below.[57] This is consistent with current order entry period, pursuant to which orders and quotes entered for inclusion in the opening process do not execute until the opening trade pursuant to current subparagraph (a)(3). The System accepts all orders and quotes that are available for a class and trading session pursuant to Rule 6.10(a) during the Queuing Period, which are eligible for execution during the opening rotation, except as follows:

• The System rejects IOC and FOK orders during the Queuing Period;[58]

• the System accepts orders and quotes with MTP Modifiers during the

[46] The order of events that comprise this proposed opening auction process corresponds to the opening auction process on Cboe Options. *See* Cboe Options Rule 6.2.

[47] A term defined elsewhere in the Rules has the same meaning with respect to Rule 6.11, unless otherwise defined in Rule 6.11.

[48] Cboe Options similarly considers the Exchange's best quote bid and best quote offer when determining whether the Exchange's market is too wide. On Cboe Options, the term ''quote'' corresponds to the term ''bulk message'' on the Exchange. Cboe Options also considers quotes from any away markets, if it has activated Hybrid Agency Liaison (''HAL'') at the open. While the Exchange does not have a step-up mechanism that corresponds to HAL, the Exchange believes considering any quotes from away markets in addition to quotes on its own market when determining whether to open a series will enhance the opening auction price by considering all available pricing information.

[49] The Maximum Composite Width corresponds to the opening exchange prescribed width range (''OEPW'') on Cboe Options. *See* Cboe Options Rule 6.2(d)(i)(A). The Exchange will determine the Maximum Composite Width in a slightly different manner than Cboe Options determines the OEPW; however, both are based on appointed Market-Maker quotes and are intended to create a reasonable range to ensure the market does not open at extreme prices. Additionally, as proposed, the Maximum Composite Width will factor in away prices in addition to quotes on the Exchange (unlike Cboe Options which considers only quotes on the Exchange).

[50] In other words, for the RTH opening auction in an All Sessions class, the expected opening information to be disseminated in opening auction updates prior to the conclusion of the GTH trading session will be based on orders and quotes in the RTH Queuing Book (*i.e.,* RTH Only orders) and in the GTH Book (*i.e.,* All Sessions orders).

[51] Cboe Options uses the OEPW as the range within which the opening price must be. *See* Cboe Options Rule 6.2(d)(i)(C). The Exchange will determine the Opening Collar in a slightly different manner than Cboe Options determines the OEPW; however, both are based on appointed Market-Maker quotes and are intended to create a reasonable range to ensure the market does not open at extreme prices. Additionally, as proposed, the Opening Collar will factor in away prices in addition to quotes on the Exchange (unlike Cboe Options which considers only quotes on the Exchange).

[52] *See* current Rule 6.11(a)(2).

[53] In other words, at 7:30 a.m., All Sessions orders will rest on the GTH Queuing Book and be eligible to participate in the GTH opening auction process, and RTH Only orders will rest on the RTH Queuing Book and be eligible to participate in the RTH opening auction process.

[54] *See* current Rule 6.11(a)(1) (the current rule does not use the term ''Queuing Period''; however, it does provide for a time prior to the opening of a series during which the System accepts orders and quotes).

[55] *See* proposed Rule 6.11(b)(1).

[56] Pursuant to Cboe Options Rule 6.2(a), the pre-opening period (equivalent to the proposed Queuing Period) begins no earlier than 2:00 a.m. Central time for regular trading hours and no later than 4:00 p.m. on the previous day for global trading hours (as global trading hours on Cboe Options begins at 2:00 a.m. Central time). The Exchange does not propose to have flexibility as Cboe Options has, and believes the proposed time period for the Queuing Period is sufficient.

[57] The proposed rule change moves the provision that states that GTC and GTD orders remaining on the Book from the previous trading day may participate in the opening process from current paragraph (b) to the definition of Queuing Book in proposed paragraph (a).

[58] *See* current subparagraph (a)(1) and proposed subparagraph (a)(2)(A); *see also* Cboe Options Rule 6.2(a)(i).

Queuing Period, but does not enforce them during the opening rotation;[59]

• the System accepts stop and stop-limit orders[60] during the Queuing Period, but they do not participate during the opening rotation. The System enters any of these orders it receives during the Queuing Period into the Book following completion of the opening rotation (in time priority);[61]

• the System converts all ISOs received prior to the completion of the opening rotation into non-ISOs;[62] and

• complex orders do not participate in the opening auction described in Rule 6.11 and instead may participate in the COB Opening Process pursuant to Rule 6.13(c).[63]

Proposed paragraph (c) describes the opening auction updates the Exchange will disseminate as part of the opening auction process. As noted above, opening auction updates contain information regarding the expected opening of a series. These messages provide market participants with information that may contribute to enhanced liquidity and price discovery during the opening auction process. Beginning at a time (determined by the Exchange) no earlier than one hour prior to the expected initiation of the opening rotation for a trading session and until the conclusion of the opening rotation for a series, the Exchange disseminates opening auction updates for the series.[64] The Exchange disseminates opening auction updates at regular intervals of time (the length of which the Exchange determines for each trading session), or less frequently if there are no updates to the opening information since the previously disseminated update, to all subscribers to the Exchange's data feeds that deliver these messages until a series opens.[65] If there have been no changes since the previous update, the Exchange does not believe it is necessary to disseminate duplicate updates to market participants at the next interval of time.

Proposed paragraph (d) describes the events that will trigger the opening rotation for a class. Pursuant to current subparagraph (a)(1), the System will open series in random order, staggered over regular intervals of time after a time period following the first transaction in the securities underlying the options on the primary market that is disseminated after 9:30 a.m. (with respect to equity options) or following 9:30 a.m. (with respect to index options). As proposed for Regular Trading Hours, after a time period (which the Exchange determines for all classes) following the System's observation after 9:30 a.m. of the first disseminated (1) transaction price for the security underlying an equity option or (2) index value for the index underlying an index option, the System will initiate the opening rotation for the series in that class, and the Exchange disseminates message to market participants indicating the initiation of the opening rotation.[66] For Global Trading Hours, the System will initiate the opening rotation at 8:30 a.m.[67]

Proposed paragraph (e) describes the opening rotation process, during which the System will determine whether the Composite Market for a series is not wider than a maximum width, will determine the opening price, and open series.[68] The Maximum Composite Width Check and Opening Collar are intended to ensure that series open in a fair and orderly manner and at prices consistent with the current market conditions for the series and not at extreme prices, while taking into consideration prices disseminated from other options exchanges that may be better than the Exchange's at the open.

Proposed subparagraph (e)(1) describes the Maximum Composite Width Check.

• If the Composite Width of a series is less than or equal to the Maximum Composite Width, the series is eligible to open (and the System determines the Opening Price as described below).

• If the Composite Width of a series is greater than the Maximum Composite Width, but there are no non-M Capacity[69] market orders or buy (sell) limit orders with prices higher (lower) than the Composite Bid (Offer) and there are no locked or crossed orders or quotes, the series is eligible to open (and the System determines the Opening Price as described below).

• If neither of the conditions above are satisfied for a series, the series is ineligible to open. The Queuing Period for the series continues (including the dissemination of opening auction updates) until one of the above conditions for the series is satisfied.[70]

[59] *See* current subparagraph (a)(1) and proposed subparagraph (a)(2)(B). Cboe Options has Market-Maker trade prevention orders, which it does not accept prior to the opening. *See* Cboe Options Rule 6.2(a)(i).

[60] Pursuant to Rule 6.10(b), stop and stop-limit orders are triggered based on the consolidated last sale price. Not participating in the opening process is consistent with this requirement, as the Exchange needs to be open (and thus have an opening trade occur) in order for there to be a consolidated last sale price that can trigger these orders.

[61] This is consistent with current functionality, and the proposed rule change is adding this detail to the Rules. *See also* Cboe Options Rule 6.2(c)(i)(B) (which states that order with a stop contingency do not participate in the opening rotation).

[62] *See* current subparagraph (a)(1) and proposed subparagraph (a)(2)(D); *see also* Cboe Options Rule 6.2(a)(i) (which does not permit ISOs to be entered during the Cboe Options pre-opening period).

[63] *See* current subparagraph (a)(1) and proposed subparagraph (a)(2)(E); *see also* Cboe Options Rule 6.2(c)(i)(B).

[64] The Exchange only begins disseminating updates for series with locked or crossed interest or if the series needs Market-Maker bulk messages. There can only be an expected opening price to disseminate if these conditions have been met, and thus no updates will be disseminated if these conditions do not exist. *See also* Cboe Options Rule 6.2(a)(ii) (which provides that Cboe Options may begin disseminated expected opening information (''EOIs'') messages (which correspond to opening auction updates)). Cboe Options currently begins disseminating EOIs at 7:30 a.m. or 8:00 a.m. Central time (depending on the class), which is consistent with the proposed rule change to begin dissemination of opening auction messages no earlier than one hour prior to the expected initiation of the opening rotation for a series. The Exchange believes market participants generally want to receive this information closer to the opening of trading.

[65] *See also* Cboe Options Rule 6.2(a)(ii) (Cboe Options will similarly disseminate EOIs at regular intervals or less frequently if there are no updates, and will not disseminate EOIs in certain circumstances, including if there is no locked or crossed interest (because there would be no expected opening price or size)).

[66] *See* current subparagraph (a)(1), pursuant to which the opening will be triggered upon the occurrence of similar events after a time period determined by the Exchange.

[67] *See also* Cboe Options Rule 6.2(b). Unlike Cboe Options, the opening rotation will be triggered in all equity classes by observation of the first transaction in the underlying security (rather than some classes being triggered by a timer), and the opening rotation will be triggered in all index classes by observation of the first index value (rather than some classes being triggered by a timer). The Exchange does not believe it needs this flexibility.

[68] *See also* Cboe Options Rule 6.2(d) (pursuant to which Cboe Options will generally not open a series if the width is wider than an acceptable price range or if the opening trade price is outside of an acceptable price range). The Exchange will similarly have a maximum quote width and acceptable opening price range, however, they may be calculated differently. Cboe Options has additional opening conditions that the Exchange does not propose to adopt.

[69] Capacity M is used for orders for the account of a Market-Maker (with an appointment in the class). *See* Rule 1.1 (definition of Capacity).

[70] *See* Cboe Options Rule 6.2(c)(iii) (pursuant to which the opening rotation period on Cboe Options continues, including dissemination of EOIs, until the opening conditions are satisfied). The Exchange may also open a series pursuant to current paragraph (c) (proposed paragraph (h)), which permits the Exchange to deviate from the standard manner of the opening auction process, including adjusting the timing of the opening rotation in any class, modifying any time periods described in Rule 6.11, and delaying or compelling the opening of a series if the opening width is wider than Maximum Width, when it believes it is necessary in the interests of a fair and orderly market. The proposed rule change specifies additional ways in which the Exchange may deviate from the standard of opening (which it has the authority to do under the current rule). *See also* Cboe Options Rule 6.2(e) (pursuant to which Cboe Options may deviate from the standard manner of the opening auction process for the same reasons). The Exchange will continue to make and maintain records to document all determinations to deviate from the standard manner of the opening auction process, and periodically reviews these determinations for consistency with the interests of a fair and orderly market.

The Exchange will use the Maximum Composite Width Check as a price protection measure to prevent orders from executing at extreme prices at the open. If the width of the Composite Market (which represents the best market, as it is comprised of the better of Market-Maker bulk messages on the Exchange or any away market quotes) is no greater than the Maximum Composite Width, the Exchange believes it is appropriate to open a series under these circumstances and provide marketable orders with an opportunity to execute at a reasonable opening price (as discussed below), because there is minimal risk of execution at an extreme price. However, if the Composite Width is greater than the Maximum Composite Width but there are no non-M Capacity orders [71] that lock or cross the opposite-side widest point of the Composite Market (and thus not marketable at a price at which the Exchange would open, as described below), there is similarly no risk of an order executing at an extreme price on the open. Because the risk that the Maximum Composite Width Check is intended to address is not present in this situation, the Exchange believes it is appropriate to open a series in either of these conditions. However, if neither of these conditions is satisfied, the Exchange believes there may be risk that orders would execute at an extreme price if the series open, and therefore the Exchange will not open a series.

Proposed subparagraph (e)(2) describes how the System determines the Opening Trade Price for a series after it satisfies the Maximum Composite Width Check described above.

- The Opening Trade Price is the price that is not outside the Opening Collar and:
  - ○ The price at which the largest number of contracts can execute (*i.e.,* the volume-maximizing price);
  - ○ if there are multiple volume-maximizing prices, the price at which the fewest number of contracts remain unexecuted (*i.e.,* the imbalance-minimizing price); or
  - ○ if there are multiple volume-maximizing, imbalance-minimizing prices, (1) the highest (lowest) price, if there is a buy (sell) imbalance, or (2) the price at or nearest to the midpoint of the Opening Collar, if there is no imbalance.
- There is no Opening Trade Price if there are no locked or crossed orders or quotes at a price not outside the Opening Collar.[72]

The Exchange believes the proposed volume-maximizing, imbalance-minimizing procedure is reasonable, as it will provide for the largest number of contracts in the Queuing Book that can execute, leaving as few as possible bids and offers in the Book that cannot execute.[73] The Exchange will use the Opening Collar as a price protection measure to prevent orders from executing at extreme prices at the open. If the Opening Trade Price is not outside the Opening Collar (which will be based on the best then-current market), the Exchange believes it is appropriate to open a series at that price, because there is minimal risk of execution at an extreme price. However, if the Opening Trade Price would be outside of the Opening Collar, the Exchange believes there may be risk that orders would execute at an extreme price if the series open, and therefore the Exchange will not open a series.

The following examples show the application of the Maximum Composite Width Check:

Example #1

Suppose the Maximum Composite Width for a class is 0.50, and the Composite Market is 1.00 × 2.00, comprised of an appointed Market-Maker bulk message bid of 2.00 and an appointed Market-Maker bulk message offer of 1.00. There is no other interest in the Queuing Book. The series is not eligible to open, because the width of the Composite Market is greater than the Maximum Composite Width but there are locked orders or quotes in the series. The Queuing Period for the series will continue until the series satisfies the Maximum Composite Width Check.

Example #2

Suppose the Maximum Composite Width for a class is 0.50, and the Composite Market is 1.00 × 2.00, comprised of an appointed Market-Maker bulk message bid of 1.00 and an appointed Market-Maker bulk message offer of 2.00. There is no other interest in the Queuing Book. The series is eligible to open, because the width of the Composite Market is greater than the Maximum Composite Width and there are no locked orders or quotes in the series or non-M Capacity orders. The System will then determine the Opening Trade Price.

Example #3

Suppose the Maximum Composite Width for a class is 0.50, and the Composite Market is 1.00 × 2.00, comprised of an appointed Market-Maker bulk message bid of 1.00 and an appointed Market-Maker bulk message offer of 2.00. There is a non-M Capacity limit order to buy for $1.99 in Queuing Book. The series is not eligible to open, because the width of the Composite Market is greater than the Maximum Composite Width, and there is a non-M Capacity order at a price inside of the Composite Market. The Queuing Period for the series will continue until the series satisfies the Maximum Composite Width Check.

Pursuant to proposed subparagraph (e)(3), if the System establishes an Opening Trade Price, the System will execute orders and quotes in the Queuing Book at the Opening Trade Price. The System will prioritize orders and quotes in the following order: Market orders, limit orders and quotes with prices better than the Opening Trade Price, and orders and quotes at the Opening Trade Price.[74] The System allocates orders and quotes at the same price pursuant to the allocation algorithm that applies to a class intraday (in accordance with Rule 6.12), unless the Exchange determines to apply a different allocation algorithm from Rule 6.12 to a class during the opening rotation.[75] If there is no Opening Trade Price, the System opens a series without a trade.

Pursuant to proposed subparagraph (f), as is the case today, following the conclusion of the opening rotation, the System enters any unexecuted orders and quotes (or remaining portions) from the Queuing Book into the Book in time sequence (subject to a User's

[71] Market-Maker bulk messages are considered when determining the Composite Market. The Exchange believes it is appropriate to consider Market-Maker bulk messages when determining an opening quote to ensure there will be liquidity in a series when it opens. Additionally, while it is possible for Market-Makers to submit M orders, the Exchange believes there is less risk of a Market-Maker inputting an order at an extreme price given that Market-Makers are generally responsible for pricing the market.

[72] *See* current Rule 6.11(a)(2)(A).

[73] *See also* Cboe Options Rule 6.2(c)(i)(A) (pursuant to which Cboe Options will open at the market-clearing price, and if there are multiple prices at which the same number of contracts would clear, Cboe Options will use similar tie-breakers).

[74] *See* current Rule 6.11(a)(3) (which states the System will prioritize orders and quotes that are price equal to or more aggressively than the Opening Price); *see also* Cboe Options Rule 6.2(c)(i)(C). The Exchange believes it is appropriate to prioritize orders with the most aggressive prices, as it provides market participants with incentive to submit their best-priced orders.

[75] *See* Cboe Options Rule 6.2, Interpretation and Policy .04. While the allocation algorithm used during the opening rotation for a class will default to and generally be the same as the one used for that class intraday, the Exchange believes the flexibility is appropriate so that it can facilitate a robust opening with sufficient liquidity in all classes. Cboe Options may apply a different allocation algorithm for series that open at a minimum price increment due to a sell market order imbalance. The Exchange does not believe it needs this flexibility.

instructions—for example, a User may cancel an order), where they may be processed in accordance with Rule 6.12. Consistent with the OPG contingency (and current functionality), the System cancels any unexecuted OPG orders (or remaining portions) following the conclusion of the opening rotation.

The proposed rule change makes nonsubstantive changes to current paragraphs (b) and (d) (proposed paragraphs (g) and (i), respectively) to reflect the proposed defined terms and to make the provision more plain English.

Currently, if an order enters the Book following the Opening Process (which would include any GTC or GTD orders that reenter the Book from the prior trading day) and becomes subject to the drill-through protection pursuant to Rule 6.14(a)(4), the NBO (NBB) that existed at the time it enters (or reenters) the Book would be used when determining the drill-through price. Proposed Rule 6.14(a)(4)(A) provides that if an order that enters the Book following the Opening Auction Process and becomes subject to the drill-through protection, the bid (offer) limit of the Opening Collar plus (minus) the buffer amount will be the drill-through price.[76] As discussed above, the Opening Collar is a price protection, and the Exchange would execute orders at the open at prices at or within the Opening Collar (as it would execute orders at or within the NBBO). Therefore, the Exchange believes the Opening Collar limit price points are reasonable to use when determining the drill-through price for orders that are unable to execute during the opening rotation.

Trading Hours and Halts for Index Options

Currently, the Exchange lists for trading options on the Russell 2000 Index (''RUT options''), and as noted above, the Exchange intends to list DJX options in connection with the launch of the GTH trading session. Pursuant to current Rule 6.1(a), the Exchange has determined that Regular Trading Hours for these index options are (or will be, with respect to DJX options) from 9:30 a.m. to 4:15 p.m. Proposed Rule 6.1(b)(2) provides that Regular Trading Hours for index options will be from 9:30 a.m. to 4:15 p.m., except for index options the Exchange designates to remain open for trading until 4:00 p.m. This is consistent with the current rule, pursuant to which trading for index options will end at 4:00 p.m. or 4:15 p.m. However, as proposed, Regular Trading Hours for an index option will default to a closing time of 9:30 a.m. to 4:15 p.m. (rather than until 4:00 p.m.), as the Exchange expects most index options to have a closing time of 4:15 p.m., and the Exchange will have authority to determine to have trading for an index option stop at 4:00 p.m.

Pursuant to Chapter 24, the Exchange may list for trading options on indexes that satisfy the criteria in Cboe Options Rule 24.2.[77] However, pursuant to Chapter 24, Cboe Options Rule 24.6, which sets forth the trading days and hours for index options that may be listed pursuant to Cboe Options Rule 24.2, does not apply to the Exchange. Because the Exchange may determine to list other index options pursuant to Cboe Options Rule 24.2, the Exchange proposes to add the trading hours for all index options the Exchange may determine to list for trading on its Exchange in the future, even though it currently only lists one index option, and plans to list another index option in the near future, for trading during the hours set forth in current Rule 6.1(a).[78] The proposed trading hours for index options in proposed Rule 6.1(b)(2) correspond to the same trading hours for those index options in Cboe Options Rule 24.6.

Proposed Rule 6.1(b)(2)(A) states the last trading day for A.M.-settled index options is the business day prior to the expiration date of the specific series. This will ensure trading in these options do not continue for an entire trading day after the settlement value has been determined. This is consistent with current trading hours for A.M.-settled index options on the Exchange (currently, the Exchange lists A.M.-settled options on the Russell 2000 Index (''RUT'') for trading and intends to list A.M.-settled DJX options for trading), and is consistent with the last trading day for expiring A.M.-settled index options on Cboe Options.[79]

Proposed Rule 6.1(b)(2)(B) states on their last trading day, Regular Trading Hours for the following options are from 9:30 a.m. to 4:00 p.m.:

- Cboe S&P 500 AM/PM Basis options
- Index Options with Nonstandard Expirations (*i.e.,* Weeklys and EOMs) and Quarterly Expirations (*i.e.,* QIXs)
- SPX options (p.m.-settled)
- XSP options (p.m.-settled)

Generally, these options are priced in the market based on corresponding futures values. On the last day of trading, the closing prices of the component stocks (which are used to derive the exercise settlement value) are known at 4:00 p.m. (or soon after) when the equity markets close. Despite the fact that the exercise settlement value is fixed at or soon after 4:00 p.m., if the Exchange did not close trading in these expiring options on their last trading day, trading in these options would continue for an additional fifteen minutes until 4:15 p.m. and would not be priced on corresponding futures values, but rather the known cash value. At the same time, the prices of non-expiring series continue to move and be priced in response to changes in corresponding futures prices.

Because of the potential pricing divergence that could occur between 4:00 and 4:15 p.m. on the final trading day of these expiring options (*e.g.,* switch from pricing off of futures to cash), the Exchange believes that, in order to mitigate potential investor confusion, it is appropriate to cease trading in these expiring options at 4:00 p.m. on the last day of trading. The proposed change to the close of trading hours will apply to all outstanding expiring expirations for the above classes or series types listed on or before the effective date of this proposal.

Additionally, these are the same Regular Trading Hours for these options on their last trading day on Cboe Options.[80]

Proposed Rule 6.1(b)(2)(C) states on their last trading day, Regular Trading Hours for expiring FTSE Developed Europe Index options are from 9:30 a.m. to the closing time of the London Stock Exchange, which is usually 11:30 a.m. The Exchange is proposing that expiring FTSE Developed Europe Index options trade only during a portion of the day on their expiration date to align the trading hours of expiring FTSE Developed Europe Index options with expiring FTSE Developed Europe Index futures. FTSE Developed Europe Index futures trade on CME and stop trading at 10:30 a.m. (Chicago time) on the third Friday of the futures contract month.[81] Additionally, these are the same Regular Trading Hours for these options on their last trading day on Cboe Options.[82]

Proposed Rule 6.1(b)(2)(D) provides that the last trading day for MSCI EAFE Index options and MSCI Emerging

[76] The proposed rule change makes corresponding changes to proposed Rule 6.14(a)(4)(B).

[77] Pursuant to Chapter 24, the Exchange incorporates by reference Cboe Options Rule 24.2.

[78] The Exchange has no current plans to list additional index options for trading.

[79] *See* Cboe Options Rule 24.9(a)(4).

[80] *See* Cboe Options Rules 24.6, Interpretations and Policies .01 (QIXs), .03 (Cboe S&P 500 AM/PM Basis options), and .04 (P.M.-settled SPX and XSP options), and 24.9(e)(4) (Nonstandard Expirations).

[81] *See* CME Rule 39002.G, available at: *http://www.cmegroup.com/rulebook/CME/IV/350/390.pdf.*

[82] *See* Cboe Options Rule 24.6, Interpretation and Policy .05.

Markets Index options will be the business day prior to the expiration date of the specific series. MSCI EAFE and MSCI Emerging Markets Index options are p.m.-settled, which means the exercise settlement value of an expiring option is derived from the closing prices of the underlying components on the series expiration date. Each of these indexes consists of components from over 20 countries. Because the components of each of these indexes encompass multiple markets around the world, the components are subject to varying trading hours. For the MSCI EAFE Index, the first components open trading at approximately 6:00 p.m. Eastern time on the prior trading day, and the last components end trading at approximately 12:30 a.m. Eastern time. Similarly, for the MSCI Emerging Markets Index, the first components open trading at approximately 7:00 p.m. Eastern time on the prior trading day, and the last components end trading at approximately 4:30 p.m. Eastern time.

Because trading in various components would end prior to the beginning of MSCI EAFE and Emerging Market Index options Regular Trading Hours (*i.e.,* 9:30 a.m. Eastern time),[83] the closing prices of those components, which would be used to determine the exercise settlement value, would be determined prior to the time when the expiring options may begin trading on the expiration date. This increases the risk of providing liquidity in these products on that date. Generally, the prices of futures on these indexes can be a proxy for the current level of the applicable index when options on those indexes are trading on the Exchange while the index level is not being disseminated. However, that is not the case on options' expiration dates, as the prices that will be used to determine the exercise settlement value are fixed once trading in the components ends, and thus futures trading prices after trading in those components end have no bearing on the exercise settlement value. Therefore, the Exchange believes it is appropriate to stop trading in expiring MSCI EAFE and Emerging Markets Index options on the business day prior to the expiration date. As proposed, on their last day of trading (the trading day prior to the expiration date), MSCI EAFE and Emerging Markets Index options would trade from 9:30 a.m. through 4:15 p.m. Eastern time. The proposed trading hours for these index options on their last trading day is also the same as the trading hours for those index options on Cboe Options.[84]

Proposed Rule 6.1(b)(2)(E) states with respect to options on a foreign index that is comprised of component securities trading in a single country, the Exchange may determine to not open the options for trading when the component securities of the foreign index are not trading due to a holiday for the foreign exchange(s) on which the component securities trade. The Exchange announces the days on which options on a particular foreign index will be closed at least once a year in January. Current Rule 6.1(c) (proposed Rule 6.1(d)) identifies the days on which the Exchange is not open due to a holiday.[85] Exchanges in foreign countries also have their own holiday schedules.[86] If the Exchange determines to list for trading options that overlie various foreign indexes,[87] the components of which trade on foreign exchanges, the Exchange proposes to specify in its Rules that the Exchange may determine to not open options on foreign indexes when the component securities of the foreign index are not open for trading due to a holiday on the foreign exchange; however, the Exchange proposes to limit the application of this proposal to options on foreign indexes that are comprised of component securities trading in a single country.[88]

The Exchange may trade options on various foreign indexes after trading in all component securities has closed for the day and the index level is no longer widely disseminated at least once every fifteen seconds, provided that futures on the applicable indexes are trading and prices for those contracts may be used as a proxy for the current index value.[89] For example, the component securities of the FTSE China 50 Index open with the start of trading on the Stock Exchange of Hong Kong (''SEHK'') at approximately 9:30 p.m. Eastern time (prior day) and close with the end of trading on the SEHK at approximately 4:00 a.m. Eastern time (next day). Thus, between 9:30 a.m. and 4:15 p.m. Eastern time, the FTSE China 50 Index level is a static value that market participants can access via data vendors. However, if the Exchange has FTSE China 50 options listed, the Exchange would continue to trade options on the FTSE China 50 Index (''China 50 options'') from 9:30 a.m. to 4:15 a.m. Eastern time because prices of the E-Mini FTSE China 50 Index futures trading at the CME may be used as a proxy for the current index value.[90] When SEHK is closed because of a holiday, E-Mini FTSE China 50 Index futures remain open and may still be used as a proxy for the current index value. However, the Exchange may determine to keep China 50 Options (as well as other options on other foreign indexes) closed because of a holiday on SEHK (or the applicable foreign exchange on which the index constituents trade).

For example, SEHK was closed February 5 through 7 of 2019 for the Lunar New York. Although E-Mini FTSE China 50 Index futures can be used as a proxy, the Exchange may have determined that options participants would be better served by keeping China 50 options closed because the holiday caused the underlying index value to be unavailable for an extended period of time.

The Exchange has authority to determine trading hours for index options, and to change them if it determines there are unusual conditions.[91] This proposed rule change simply seeks to add a rule provision to notify market participants that the Exchange may determine not to open options on foreign indexes because of a holiday on a foreign exchange. Furthermore, as proposed, the Exchange

[83] Trading in the other components ends at various times throughout the trading day.

[84] *See* Cboe Options Rule 24.6, Interpretation and Policy .05.

[85] The Exchange is not open for business on New Year's Day, Martin Luther King, Jr. Day, Presidents' Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, or Christmas Day. When any holiday observed by the Exchange falls on a Saturday, the Exchange will not be open for business on the preceding Friday, and when any holiday observed by the Exchange falls on a Sunday, the Exchange will not be open for business on the following Monday, unless unusual business conditions exist at the time.

[86] *See, e.g.,* Stock Exchange of Hong Kong Holiday Schedule, available at: *https://www.hkex.com.hk/eng/market/sec_tradinfo/tradcal/nont10.htm* and London Stock Exchange Holiday Schedule, available at: *http://www.lseg.com/areas-expertise/our-markets/london-stock-exchange/equities-markets/trading-services/business-days.*

[87] Pursuant to Cboe Options Rule 24.2, Interpretations .01 through .03, the Exchange may list options on the following foreign indexes: MSCI EAFE Index, MSCI Emerging Markets Index, FTSE Emerging Index, FTSE Developed Europe Index, FTSE 100 Index, and FTSE China 50 Index. As noted above, the Exchange does not currently list options on any of these indexes.

[88] When there are multiple exchanges in a single country trading the component securities of a foreign index, the holiday schedule for exchanges within that country are likely to be the same or similar.

[89] *See* Rules 24.2.01(a)(8), 24.2.02(a)(8), and 24.2.03(a)(8).

[90] The trading hours for E-Mini FTSE China 50 Index Futures are from 6:00 p.m. to 5:00 p.m. Eastern time the following day, Sunday through Friday. *See* E-Mini FTSE China 50 Index Future Contract specifications located at: *http://www.cmegroup.com/education/files/e-mini-ftse-china-50-index-futures.pdf.* The Exchange believes E-Mini FTSE China 50 Index Futures are an appropriate proxy for China 50 options.

[91] *See* current Rule 6.1(b) (proposed Rule 6.1(b)(2)).

will announce to market participants via Exchange Notice in January of every year (and more frequently if the Exchange determines that to be necessary) the particular days on which options on particular foreign indexes will not be open due to a holiday on a foreign exchange or exchanges.

Although keeping options trading closed because of a foreign exchange's holidays will cause users of these particular options to not be able to trade when the U.S. market is otherwise open, the closures will only occur a few times a year. Furthermore, users will have sufficient notice of such closures via Exchange Notice that will be published every January. Finally, this proposal may potentially allow users to receive better executions because for certain holidays, such as during the Lunar New Year described above, the closing of the component securities may not allow Market-Makers to quote as tightly and aggressively as they would otherwise. In effect, limiting users' ability to trade particular index options to days on which there is not a holiday on a foreign exchange may better serve users because they will be trading on days in which Market-Makers may potentially provide tighter markets. Additionally, Cboe Options has the same rule.[92]

Pursuant to Chapter 24, Cboe Options Rule 24.7, which sets forth the trading days and hours for index options that may be listed pursuant to Cboe Options Rule 24.2, does not apply to the Exchange. Current Rule 6.32(a) states the Exchange may halt trading in any class in the interests of a fair and orderly market. It also lists factors, among others, the Exchange may consider when determining whether to halt trading in a class. Several factors would apply to any class (*i.e.,* equity or index), such as:

- Occurrence of an act of God or other event outside the Exchange's control;
- occurrence of a System technical failure or failures including, but not limited to, the failure of a part of the central processing system, a number of Trading Permit Holder trading applications, or the electrical power supply to the System itself or any related system; or
- other unusual conditions or circumstances are present.[93]

Current Rule 6.32(a)(1) and (2) (proposed Rule 6.32(a)(1)(A) and (B)) provides factors the Exchange may consider when determining whether to halt trading in an equity option class. However, there are specific factors the Exchange may consider when determining whether to halt trading in an index option class, and the proposed rule change adds those to proposed Rule 6.32(a)(2):

- The extent to which trading in the stocks or options underlying the index is not occurring;
- the current calculation of the index derived from the current market prices of the stock;
- the ''current index level'' (which is the implied forward level based on volatility index (security) futures prices) for a volatility is not available or the cash (spot) value for a volatility index is not available;[94] or
- the activation of price limits on futures exchanges or the halt of trading in related futures.

Rule 6.32 does not restrict the factors the Exchange may consider when determining whether to halt trading in a class; the factors listed in paragraph (a) (currently and as proposed) are examples of factors the Exchange may consider. Therefore, the Exchange already has authority to consider these factors when determining whether to halt trading in an index option class, as changes in these factors would likely be considered unusual circumstances and would likely be considered to determine whether these changes have an impact on a fair and orderly market for the index options. The proposed rule change provides transparency to investors regarding the factors the Exchange may consider when determining to halt trading in an index option class, as Rule 6.32 currently does for equity option classes. Additionally, these factors are listed as factors Cboe Options may consider when determining whether to halt trading in an index option class.[95]

Additionally, proposed Rule 6.32(e) states that when the primary market for a security underlying the current index value of an index option does not open for trading, halts trading prematurely, or otherwise experiences a disruption of normal trading on a given day, or if a particular security underlying the current index option does not open for trading, halts trading prematurely, or otherwise experiences a disruption of normal trading on a given day in its primary market, the price of that security is determined, for the purposes of calculating the current index value at expiration, in accordance with the Rules and By-Laws of The Options Clearing Corporation (''OCC''). Investors who trade index options against the underlying stocks as well as those who trade the index options against index futures generally rely upon the final settlement value of index options converging with the corresponding values of the underlying index or index future. Without this convergence, investors may face significant unexpected exposure to market risk. Many public customers and market-makers use index options to hedge ''cash'' positions they hold in the stocks which make up the index. The Exchange's Rules are currently silent regarding the calculation of the settlement value for an index option if the above circumstances exist. The Exchange believes the proposed rule change provides transparency with the respect to the process the Exchange will use in the event the above circumstances transpire and assures convergence at settlement between the value of index options and index futures and thus minimizes these risks. OCC's Rules and By-Laws provide OCC with broad discretionary authority to adjust settlement values for OCC-cleared index options and futures whenever, and in whatever manner, OCC deems appropriate to avoid a disconnect between the futures and options markets or among the futures markets.[96] Cboe Options has the same provision in its rules.[97]

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.[98] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[99] 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 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.

[92] *See* Cboe Options Rules 24.6, Interpretation and Policy .06.

[93] *See* Rule 6.32(a)(3)–(5) and.

[94] The Exchange does not currently list, and has no current plans to list, options on a volatility index.

[95] *See* Cboe Options Rule 24.7(a)(ii) and (iii), and Interpretations and Policies .01 and .03.

[96] *See* OCC By-Laws Articles XII, Section 5 and XVII, Section 4; *see also* Securities Exchange Act Release No. 46561 (September 26, 2002), 67 FR 61943 (October 2, 2002) (SR–OCC–2002–09).

[97] *See* Cboe Options Rule 24.7(e).

[98] 15 U.S.C. 78f(b).

[99] 15 U.S.C. 78f(b)(5).

Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [100] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change to adopt Global Trading Hours will remove impediments to and perfect the mechanism of a free and open market and a national market system. Global Trading Hours is a competitive initiative designed to improve the Exchange's marketplace for the benefit of investors. The proposed rule change provides a new investment opportunity within the options trading industry that is consistent with the continued globalization of the securities markets and closer aligns the Exchange's trading hours with extended trading hours of stock exchanges. The Exchange believes the proposed rule change will enhance competition by providing a service to investors that most other options exchanges currently are not providing. The Exchange believes the competition among exchanges ultimately benefits the entire marketplace. Given the robust competition among the options exchanges, innovative trading mechanisms are consistent with the above-mentioned goals of the Exchange Act.

The proposed rule change also provides a mechanism for the Exchange to more effectively compete with exchanges located outside of the United States. Global markets have become increasingly interdepending and linked, both psychologically and through improved communications technology. This has been accompanied by an increased desire among investors to have access to U.S.-listed exchange products outside of Regular Trading Hours, and the Exchange believes this desire extends to its exclusively listed products. The Exchange believes that the proposed rule change is reasonably designed to provide an appropriate mechanism for trading outside of Regular Trading Hours while providing for appropriate Exchange oversight pursuant to the Act, trade reporting, and surveillance.

While only one other options exchange is currently open for trading outside of Regular Trading Hours, the Commission has authorized stock exchanges to be open for trading outside of these hours pursuant to the Act. Additionally, futures exchanges also operate outside of those hours. Thus, the proposed rule change to adopt Global Trading Hours is not novel or unique. The Exchange has currently authorized one class to list for trading during Global Trading Hours. As the proposed rule change is a new Exchange initiative, the Exchange believes it is reasonable to trade a limited number of classes upon implementation for which demand is believed to be the highest during Global Trading Hours.

The vast majority of the Exchange's trading rules will apply during Global Trading Hours in the same manner as during Regular Trading Hours, which rules have all be previously filed with the Commission as being consistent with the goals of the Act. Rules that will apply equally during Global Trading Hours include rules that protect public customers, impose best execution requirements on Trading Permit Holders, and prohibit acts and practices that are inconsistent with just and equitable principles of trade as well as fraudulent and manipulative practices. The proposed rule change also provides opportunities for price improvement during Global Trading Hours and applies the same allocation and priority rules that are available to the Exchange during Regular Trading Hours. The Exchange believes, therefore, that the rules that will apply during Global Trading Hours will continue to promote just and equitable principles of trade and prevent fraudulent and manipulative acts.

The proposed rule change clearly identifies the ways in which trading during Regular Trading Hours will different from trading during Global Trading Hours (such as identifying order types and instructions that will not be available during Global Trading Hours). This ensures that investors are aware of any differences among trading sessions. The Exchange believes the differences are consistent with the expected differences in liquidity, participation, and trading activity between Regular Trading Hours and Global Trading Hours. The flexibility provided to the Exchange to make determinations for each trading session will allow the Exchange to apply settings and parameters to address the different market conditions that may be present during each trading session. Additionally, to further protect investors from any additional risks related to trading during Global Trading Hours, the proposed rule change requires that disclosures be made to customers describing these potential risks. The proposed All Sessions order and RTH Only order will protect investors by permitting investors who do not wish to trade during Global Trading Hours from having orders or quotes execute during those orders. Consistent with the goal of investor protection, the Exchange will not allow market orders during Global Trading Hours due to the expected increased volatility and decreased liquidity during these hours.

Additionally, the Exchange believes that the proposed rule change will foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, as the Exchange will ensure that adequate staffing is available during Global Trading Hours to provide appropriate trading support during those hours, as well as Exchange officials to make any necessary determinations under the rules during Global Trading Hours (such as trading halts and trade nullification for obvious errors). The Exchange is also committed to fulfilling its obligations as a self-regulatory organization at all times, including during Global Trading Hours. The Exchange's surveillance procedures will also be revised to incorporate transactions that occur and orders and quotations that are submitted during Global Trading Hours. The Exchange believes its surveillance procedures are adequate to properly monitor trading in DJX options during Global Trading Hours. Clearing and settlement processes will be the same for Global Trading Hours as they are for Regular Trading Hours transactions.

The proposed rule change further removes impediments to a free and open market and does not unfairly discriminate among market participants, as all Trading Permit Holders with access to the Exchange may trade during Global Trading Hours using the same connection lines, message formats data feeds, and EFIDs they use during Regular Trading Hours, minimizing any preparation efforts necessary to participate during Global Trading Hours. Trading Permit Holders will not be required to trade during Global Trading Hours.

As demonstrated above, while the proposed rule change increases the total time during which a Market-Maker with a DJX appointment must quote, this increase is de minimis given that a Market-Maker's compliance with its continuous quoting obligation is based on all classes in which it has an appointment in the aggregate. Selecting an appointment in DJX options will be optional and within the discretion of a Market-Maker. Additionally, the Exchange is providing Market-Makers with the opportunity to quote during GTH (and receive the benefits of acting as a Market-Maker with respect to transactions it effects during that time) without obtaining an additional Trading

[100] *Id.*

Permit or creating additional connections to the Exchange (as is required on Cboe Options). The Exchange believes Market-Makers will have an incentive to quote in DJX options during Global Trading Hours given the significance of the Dow Jones Industrial Average within the financial markets, the expected demand, and given that the stocks underlying the index are also trading during those hours (which may permit execution of certain hedging strategies). Extending a Market-Maker's appointment to Global Trading Hours will enhance liquidity during that trading session, which benefits all investors during those hours. The Exchange believes that the slight additional burden of extending the continuous quoting obligation to the GTH trading session in one class is outweighed by the Exchange's efforts to add liquidity in All Sessions classes, the minimal preparation a Market-Maker may require to participate in the GTH trading session, and the benefits to investors that may result from that liquidity. Therefore, the Exchange believes the proposed rule change provides customer trading interest with a net benefit, and continues to maintain a balance of Market-Maker benefits and obligations.

The proposed rule change is also consistent with Section 11A of the Act and Regulation NMS thereunder, because it provides for the dissemination of transaction and quotation information during Global Trading Hours through OPRA, pursuant to the OPRA Plan, which Commission approved and indicated to be consistent with the Act. While Section 11A and Regulation NMS contemplate an integrated system for trading securities, they also envision competition between markets, and innovation that provides marketplace benefits to attract order flow to an exchange does not result in unfair competition if other markets are free to compete in the same manner.[101]

The proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because, as noted above, another options exchange currently offers a Global Trading Hours session.[102] While there are some differences among the proposed rule change and the Cboe Options Global Trading Hours session, such as the length of the session (Cboe Options GTH trading session begins at 3:00 a.m. and the proposed Exchange GTH trading session begins at 8:30 a.m.), the participation (while all TPHs on Cboe Options will have the opportunity to participate, as all TPHs on the Exchange will, Cboe Options requires TPHs to obtain a separate GTH trading permit, log-ins, and Market-Maker appointments to participate in GTH while the Exchange will not), the proposed Exchange GTH trading session is similar to the Cboe Options GTH trading session.

The Exchange believes the proposed rule change to adopt an opening auction will protect investors, because it will enhance the openings of series on the Exchange by providing an opportunity for price discovery based on then-current market conditions. The proposed Queuing Period is substantively the same as the current Order Entry Period on the Exchange. The proposed detail regarding the Queuing Period provide additional transparency regarding the handling of orders and quotes submitted during that time, and will thus benefit investors. The proposed rule change, including orders that are not permitted during the Queuing Period or orders that are not eligible to trade during the opening rotation, is also similar to the pre-opening period on Cboe Options.[103]

The proposed rule change will protect investors by ensuring they have access to information regarding the opening of a series, which will provide them with transparency that will permit them to participate in the opening auction process and contribute to, and benefit from, the price discovery the auction may provide. The proposed opening auction updates are not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers, as all market participants may subscribe to the Exchange's data feeds that deliver these message, and thus all market participants may have access to this information.

The proposed opening rotation triggers are substantially similar to the current events that will trigger series openings on the Exchange. The proposed trigger events will remove impediments to and perfect the mechanism of a free and open market and a national market system, as they ensure that during Regular Trading Hours, the underlying securities will have begun trading, or the underlying index values will have begun being disseminated, before the System opens a series for trading. As this information will not be available during Global Trading Hours, the Exchange believes it is appropriate to begin the opening rotation for Global Trading Hours at a specified time (as Cboe Options does).

The proposed Maximum Composite Width Check and Opening Collar will protect investors by providing price protection measures to prevent orders from executing at extreme prices at the open. The Exchange believes it is appropriate to open a series under the proposed circumstances and provide marketable orders with an opportunity to execute at a reasonable opening price (as discussed below), because there is minimal risk of execution at an extreme price. These proposed price protections incorporate all available pricing information, including Market-Maker bulk messages (which are generally used to price markets for series) and any quotes disseminated from away markets, and thus may lead to a more accurate Opening Trade Price based on then-current market conditions. As noted above, Cboe Options applies similar price protections during its opening rotation. Cboe Options similarly considers Market-Maker quotes (the equivalent of Market-Maker bulk message on the Exchange), and in certain classes, quotes of away exchanges, and whether there are crossing orders or quotes when determining whether the opening width and trade price are reasonable. The Exchange proposes to calculate the maximum width and opening price range in a different, but reasonable manner intended to ensure a fair and orderly opening.

The proposed priority with respect to trades during the opening rotation are consistent with current priority principles that protect investors, which are to provide priority to more aggressively priced orders and quotes. Orders and quotes will be subject to the same allocation algorithms that the Exchange may apply during the trading day. The proposed priority and allocation of orders and quotes at the opening trade is substantially similar to the priority and allocation of orders and

[101] *See* Exchange Act Release Nos. 73704 (November 28, 2014), 79 FR 72044 (December 4, 2014) (SR–CBOE–2014–062) (approval of proposed rule change for Cboe Options to extend its trading hours outside of Regular Trading Hours); and 29237 (May 24, 1991), 46 FR 24853 (May 31, 1991) (SR–NYSe–1990–052 and SR–NYSE–1990–053) (approval of proposed rule change for NYSE to extend its trading hours outside of Regular Trading Hours). The Exchange also notes that no other U.S. options exchange provides for trading DJX options outside of Regular Trading Hours, so there is currently no need for intermarket linkage during Global Trading Hours. If another Cboe Affiliated Exchange lists DJX options outside of Regular Trading Hours, trading of DJX options on the Exchange would comply with linkage rules.

[102] *See* Cboe Options Rules 6.1 and 6.1A.

[103] *See* Cboe Options Rule 6.2(a). Cboe Options provides a longer pre-opening period than the proposed rule change. However, the Exchange is not proposing to change the time at which it begins to accept orders and quotes, believes the time period is sufficient for market participants to submit orders and quotes to participate in the opening rotation.

quotes at the opening of Cboe Options.[104]

The Exchange believes the proposed opening auction process is designed to ensure sufficient liquidity in a series when it opens and ensure series open at prices consistent with then-current market conditions, and thus will ensure a fair and orderly opening process. Additionally, as noted above, the proposed opening auction process is substantially similar to the opening auction process of Cboe Options.[105] As described above and below, the differences between proposed Rule 6.11 and Cboe Options Rule 6.2 primarily relate to differences between the exchanges, including functionality Cboe Options offers that the Exchange does not and products Cboe Options lists for trading that the Exchange does not.

The proposed rule change to add trading hours for certain index options will protect investors by providing transparency to the Rules regarding the trading hours of these index options in the event the Exchange determines to list them for trading. As noted above, the Exchange has the authority to list these options pursuant to Chapter 24, but currently does not and has no current plans to do so. Therefore, the proposed rule change has no impact on current trading of index options.

The proposed rule change regarding the last trading day for A.M.-settled index options will remove impediments to and perfect the mechanism of a free and open market and a national market system, because it clarifies current trading hours for these options and are the same trading hours for A.M.-settled index options on Cboe Options.[106]

The proposed trading hours for Cboe S&P 500 AM/PM Basis options, index options with Nonstandard Expirations and Quarterly Expirations, SPX options that are p.m.-settled, and XSP options that are p.m.-settled protects investors by preventing continue trading on a product after the exercise settlement value has been fixed, thus eliminating potential confusion. Additionally, these are the same trading hours for these series of options on Cboe Options.[107]

The proposed rule change regarding the trading hours for FTSE Developed Europe Index Options on their last trading day will protect investors, because it will eliminate pricing risk for liquidity providers on the last day of trading of expiring options in these products. The proposed hours align the trading hours of expiring FTSE Developed Europe Index options with expiring FTSE Developed Europe Index futures. FTSE Developed Europe Index futures trade on CME and stop trading at 10:30 a.m. (Chicago time) on the third Friday of the futures contract month.[108] Additionally, these are the same Regular Trading Hours for these options on their last trading day on Cboe Options.[109]

The proposed rule change regarding the last trading day for MSCI EAFE and Emerging Markets Index options will protect investors, because it will eliminate pricing risk for liquidity providers on the last trading day of expiring series in these products. The Exchange expects reduced liquidity on expiration dates of expiring EAFE and EM series due to the pricing risk associated with providing liquidity after the components whose closing prices will be used to determine the exercise settlement value of expiring options have stopped trading. Market-Makers and other liquidity providers generally price EAFE and EM options using the disseminated index values and data from the markets on which the components trade. As noted above, when these markets are not trading during U.S. trading hours, these liquidity providers price the options using prices of futures trading on the MSCI EAFE and EM indexes. While those futures prices can serve as a proxy for the index value, they cannot serve as a proxy for the settlement value on the expiration date for the options. This is because the futures pricing is intended to represent the then-current index value, but does not incorporate the closing prices of the components that will be used to determine the settlement value. This creates risk for Market-Makers and other liquidity providers, as they have no data they can use to price the expiring options based on the ultimate settlement value. This may result in trades at prices inconsistent with the settlement value of those options. The proposed rule change removes impediments to and perfects the mechanism of a free and open market by eliminating this pricing risk for liquidity providers on the last trading day of expiring series in these products. The Exchange believes this may encourage additional liquidity providers to participate on the last trading of expiring series, which may provide more competitive pricing and additional trading opportunities for expiring series, and ultimately benefits investors. Additionally, this is the same last trading for expiring series in these products as Cboe Options.[110]

The proposed rule change regarding not opening options on foreign indexes for trading when component securities are not trading will 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 by (1) limiting users' ability to trade particular index options to days on which there is not a holiday on a foreign exchange because doing so allows users of these index options to trade on days in which Market-Makers may potentially provide tighter markets and (2) providing a mechanism for notifying market participants of the days on which options on a particular foreign index will not be open due to a holiday on the foreign exchange(s) on which the index constituents trade. Additionally, Cboe Options has the same provision in its Rules.[111]

The proposed rule change is generally intended to align system functionality currently offered by the Exchange with Cboe Options functionality in order to provide a consistent technology offering for the Cboe Affiliated Exchanges. A consistent technology offering, in turn, will simplify the technology implementation, changes, and maintenance by Users of the Exchange that are also participants on Cboe Affiliated Exchanges. The Exchange believes this consistency will promote a fair and orderly national options market system. When Cboe Options migrates to the same technology as that of the Exchange and other Cboe Affiliated Exchanges, Users of the Exchange and other Cboe Affiliated Exchanges will have access to similar functionality on all Cboe Affiliated Exchanges. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The

[104] *See* Cboe Options Rule 6.2(c)(i)(C) and Interpretation and Policy .04.

[105] *See* Cboe Options Rule 6.2.

[106] *See* Cboe Options Rule 24.9(a)(4).

[107] *See* Cboe Options Rules 24.6, Interpretations and Policies .01 (QIXs), .03 (Cboe S&P 500 AM/PM Basis options), and .04 (P.M.-settled SPX and XSP options), and 24.9(e)(4) (Nonstandard Expirations).

[108] *See* CME Rule 39002.G, available at: *http://www.cmegroup.com/rulebook/CME/IV/350/390.pdf.*

[109] *See* Cboe Options Rule 24.6, Interpretation and Policy .05.

[110] *See* Cboe Options Rule 24.6, Interpretation and Policy .05.

[111] *See* Cboe Options Rule 24.6, Interpretation and Policy .06.

Exchange does not believe that the proposed rule change to adopt Global Trading Hours will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because all Trading Permit Holders will be able, but not be required, to participate during Global Trading Hours, and will be able to do so using the same connectivity as they use during Regular Trading Hours. Participation in GTH will be voluntary and within the discretion of TPHs. While the proposed rule change increases the total time during which a Market-Maker with a DJX appointment must quote, this increase is de minimis given that a Market-Maker's compliance with its continuous quoting obligation is based on all classes in which it has an appointment in the aggregate. Selecting an appointment in DJX options will be optional and within the discretion of a Market-Maker. Additionally, the Exchange is providing Market-Makers with the opportunity to quote during GTH (and receive the benefits of acting as a Market-Maker with respect to transactions it effects during that time) without obtaining an additional Trading Permit or creating additional connections to the Exchange (as is required on Cboe Options). Extending a Market-Maker's appointment to Global Trading Hours will enhance liquidity during that trading session, which benefits all investors during those hours. The Exchange believes that the slight additional burden of extending the continuous quoting obligation to the GTH trading session in one class is outweighed by the Exchange's efforts to add liquidity in All Sessions classes, the minimal preparation a Market-Maker may require to participate in the GTH trading session, and the benefits to investors that may result from that liquidity. Therefore, the Exchange believes the proposed rule change provides customer trading interest with a net benefit, and continues to maintain a balance of Market-Maker benefits and obligations.

The Exchange does not believe that the proposed rule change to adopt Global Trading Hours will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed rule change is competitive initiative that will benefit the marketplace and investors. The Exchange believes the proposed rule change will enhance competition by providing a service to investors that only one other options exchange current provides. Additionally, all options exchanges are free to compete in the same manner. The Exchange further believes that the same level of competition among options exchanges will continue during Regular Trading Hours. Because the Exchange proposes to make only exclusively listed products available for trading during Global Trading Hours, and because any All Sessions orders that do not trade during GTH will be eligible to trade during the RTH trading session in the same manner as all other orders during Regular Trading Hours, the proposed rule change will have no effect on the national best prices or trading during Regular Trading Hours. The Exchange also believes the proposed rule change could increase its competitive position outside of the United States by providing investors with an additional investment vehicle with respect to their global trading strategies during times that correspond with parts of regular trading hours outside of the United States.

The Exchange does not believe that the proposed rule change to adopt an opening auction process will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it will apply to orders and quotes of all market participants in the same manner. The same order types that are not currently accepted prior to the opening, and that do not participate in the opening process, will similarly not be accepted during the Queuing Period or be eligible for trading during the opening rotation.

The Exchange does not believe that the proposed rule change to adopt an opening auction process will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because it is designed to open series on the Exchange in a fair and orderly manner. The Exchange believes an opening auction process will enhance the openings of series on the Exchange by providing an opportunity for price discovery based on then-current market conditions. The proposed auction process will provide an opportunity for price discovery when a series opens ensure there sufficient liquidity in a series when it opens, and ensure series open at prices consistent with then-current market conditions (at the Exchange and other exchanges) rather than extreme prices that could result in unfavorable executions to market participants. Additionally, as discussed above, the proposed opening auction process is substantially similar to the Cboe Options opening auction process.[112]

The Exchange believes the proposed rule change regarding trading hours for index options will not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because those trading hours will apply to all market participants that elect to trade in those options. If the Exchange determines in the future to list these index options for trading, trading in these index options would be in the discretion of market participants. The Exchange believes the proposed rule change will not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the proposed trading hours for these index options are the same as those on another options exchange.[113]

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: (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[114] and subparagraph (f)(6) of Rule 19b–4 thereunder.[115]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings

[112] *See* Cboe Options Rule 6.2.

[113] *See* Cboe Options Rules 24.6 and 24.9(e)(4).

[114] 15 U.S.C. 78s(b)(3)(A)(iii).

[115] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–C2–2019–009 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–C2–2019–009. 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–C2–2019–009 and should be submitted on or before May 31, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[116]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–09634 Filed 5–9–19; 8:45 am]

BILLING CODE 8011–01–P

[116] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85779; File No. SR–OCC–2019–003]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Approving Proposed Rule Change To Require That an Actionable Identifier Be Included on Customer and Non-Customer Securities Options Trades Other Than Market Maker Trades

May 6, 2019.

I. Introduction

On March 20, 2019, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–OCC–2019–003 (''Proposed Rule Change'') pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 [2] thereunder to propose changes to amend OCC Rule 401 to require that an ''Actionable Identifier'' (described below) be included on certain securities options trades submitted to OCC for processing.[3] The Proposed Rule Change was published for public comment in the **Federal Register** on April 3, 2019,[4] and the Commission received no comments regarding the Proposed Rule Change. This order approves the Proposed Rule Change.

II. Background

OCC facilitates several processes by which a broker may automatically transfer an executed trade into a Clearing Member's accounts. Such transferred positions could, in certain circumstances, affect the Clearing Member's margin requirements. Currently, such a transfer may occur without the provision of information regarding the person for whom such a trade was executed.

First, OCC's Clearing Member Trade Assignment (''CMTA'') process allows a Clearing Member that executes a securities options trade (*i.e.,* the Executing Clearing Member) to send the trade directly through OCC to another Clearing Member for clearance and settlement (*i.e.,* the Carrying Clearing Member).[5] Under the CMTA process, an Executing Clearing Member may send options trades directly to a Carrying Clearing Member's omnibus accounts at OCC for clearance and settlement without providing information identifying the specific accounts to which the trade should be assigned. Second, in the ''give-up'' process, a broker may execute a transaction on an exchange and then assign that transaction to a Clearing Member's omnibus account. Specifically, for customer transactions, a broker who is not an OCC Clearing Member may execute a customer's trade and then ''give-up'' the trade to the customer's clearing broker, which must be an OCC Clearing Member, without identifying the customer for whom the transaction was executed. Similarly, a trading desk within a Clearing Member Group may execute a non-customer trade and send it to a Clearing Member's omnibus firm account without clearly identifying the account to which the trade should be allocated.[6] Finally, a broker-dealer who participates in a joint back office arrangement with a Clearing Member could execute a non-customer trade that then clears directly in a Clearing Member's omnibus firm account. Transactions executed in this way, as part of a joint back office arrangement with a Clearing Member, could result in a Clearing Member's receipt of a non-customer trade in its omnibus firm account without a clear indication of the account to which the Clearing Member should assign the trade.

According to OCC, Clearing Members have raised concerns regarding the timely account identification for trades that a Clearing Member receives through the CMTA, give-up, and joint back office processes.[7] OCC proposes to require the inclusion of an ''Actionable Identifier'' for all transactions related to a customer account or a non-customer account,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Notice of Filing *infra* note 4, 84 FR 13075.

[4] Securities Exchange Act Release No. 85441 (Mar. 28, 2019), 84 FR 13075 (Apr. 3, 2019) (SR–OCC–2019–003) (''Notice of Filing'').

[5] *See* OCC Rule 407. An ''Executing Clearing Member'' is defined in Article I, Section 1.E.(12) of OCC's By-Laws as ''a Clearing Member, on its own behalf or as the Clearing Member of an Introducing Broker that has been authorized by a Carrying Clearing Member to direct confirmed trades to be transferred to a designated account of the Carrying Clearing Member pursuant to such Clearing Members' CMTA arrangement.'' A ''Carrying Clearing Member'' is defined in Article I, Section 1.C.(12) of OCC's By-Laws as ''a Clearing Member that has authorized an Executing Clearing Member to direct the transfer of a confirmed trade to a designated account of such Carrying Clearing Member pursuant to a CMTA arrangement.''

[6] *See* Notice of Filing, 84 FR at 13077.

[7] *See* Notice of Filing, 84 FR at 13076–77.

other than Market-Maker transactions,[8] which OCC believes would allow Clearing Members to more timely identify trades as attributable to a particular customer or non-customer account.[9] As defined in the proposed amendment to Rule 401, the Actionable Identifier would consist of either a name, series of numbers, or other identifying information related to the account for which the transaction was executed. OCC would also require that each Clearing Member establish and maintain policies and procedures reasonably designed to include sufficient information in the Actionable Identifier regarding the account that originated the trade to allow the other Clearing Member to promptly clear the transaction.[10] OCC would enforce the Actionable Identifier related requirements through: (1) an annual Clearing Member certification process; and (2) a review of Actionable Identifier policies and procedures during OCC's periodic Clearing Member examinations.

In its proposal, OCC described a three-phase implementation schedule for changes pertaining to the Actionable Identifier.[11] During the first 12 months after approval of the Proposed Rule Change, the following would not constitute a violation of OCC's rules: (i) Failure to include an Actionable Identifier for transactions, or (ii) failure to maintain policies and procedures to provide that sufficient information is included in the Actionable Identifier. Second, from 13 months to 18 months after approval of the Proposed Rule Change, failure to maintain policies and procedures to provide that sufficient information is included in the Actionable Identifier would not constitute a violation of OCC's rules. Finally, beginning 19 months after approval of the Proposed Rule Change, failure to comply with any part of the rule would constitute a violation of OCC's rules, subject to the manner in which OCC enforces such violations pursuant to Rule 1201.

OCC also proposes three changes to improve the language of its Rule 401. First, OCC proposes to add the words ''in this rule'' to the last sentence of paragraph (a) of Rule 401 to clarify the scope of the sentence. Second, OCC proposes to replace the phrase ''the security type'' with the ''the product type'' in paragraphs (a)(1)(G) and (a)(2)(G) of Rule 401 to accurately describe the requirements of the rule. Finally, OCC proposes to replace the phrase ''the Give-Up Clearing Member'' with ''the Given-Up Clearing Member'' for consistency with the definition provided in Article I, Section 1.G.(3) of OCC's By-Laws.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Exchange Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to such organization.[12] After carefully considering the Proposed Rule Change, the Commission believes the proposal is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to OCC. More specifically, the Commission believes that the proposal is consistent with Section 17A(b)(3)(F) of the Exchange Act.[13]

A. Consistency With Section 17A(b)(3)(F) of the Exchange Act

Section 17A(b)(3)(F) of the Exchange Act requires that the rules of a clearing agency be designed to, among other things, (i) promote the prompt and accurate clearance and settlement of securities transactions, and (ii) foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, and (iii) in general, to protect investors and the public interest.[14] Based on its review of the record, the Commission believes that the proposed rule changes related to the Actionable Identifier are designed to promote the prompt and accurate clearance and settlement of securities transactions and foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions for the reasons set forth below.

The Actionable Identifier, as proposed, must include sufficient information regarding the account that originated a trade to allow a Clearing Member to promptly clear and settle the transaction in the appropriate account. Additionally, the Actionable Identifier would support the interactions between those firms executing transactions and those firms clearing transactions by providing information about the account to which such transactions are attributable. In this way, the proposed rule changes are designed to promote the prompt and accurate clearance and settlement of securities transactions and foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Exchange Act.

Further, the Commission believes that the proposed changes to improve the language of its Rule 401 are designed to in general, to protect investors and the public interest for the following reasons. As a general matter, enhancing the clarity of a clearing agency's rules would be in the public interest because doing so could provide information that may facilitate public interaction with the clearing agency. OCC's rules describe, in part, certain obligations of an individual submitting a trade to OCC by defining, for example, the information necessary for acceptance of such a trade. As described above, OCC proposes to revise the language of its Rule 401 to clarify the scope of the rule, more accurately state the requirements of the rule, and ensure internal consistency across OCC's rules.

Accordingly, and for the reasons stated above, the Commission believes that the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Exchange Act.[15]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Exchange Act, and in particular, the requirements of Section 17A of the Exchange Act[16] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[17] that the Proposed Rule Change (SR–OCC–2019–003) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–09630 Filed 5–9–19; 8:45 am]

BILLING CODE 8011–01–P

[8] OCC is not proposing the inclusion of an Actionable Identifier for Market-Maker transactions because OCC understands that such trades already include information that allows a Clearing Member to assign the trades to individual Market-Maker accounts. *See* Notice of Filing, 84 FR at 13076, n. 6.

[9] *See* Notice of Filing, 84 FR at 13078.

[10] OCC does not, however, propose to make the inclusion of an Actionable Identifier a prerequisite for trade acceptance.

[11] *See* Notice of Filing, 84 FR at 13078.

[12] 15 U.S.C. 78s(b)(2)(C).

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] *Id.*

[15] *Id.*

[16] In approving this Proposed Rule Change, the Commission has considered the proposed rules' impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78s(b)(2).

[18] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15943; North Carolina Disaster Number NC–00109 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of North Carolina, dated 04/30/2019.

Incident: Gas Leak Explosion.

Incident Period: 04/10/2019.

DATES: Issued on 04/30/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 01/30/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Durham.

Contiguous Counties:

North Carolina: Chatham, Granville, Orange, Person, Wake.

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for economic injury is 159430.

The State which received an EIDL Declaration # is North Carolina.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: April 30, 2019.

Christopher M. Pilkerton,

Acting Administrator.

[FR Doc. 2019–09683 Filed 5–9–19; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 10764]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Renoir: The Body, The Senses'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that the objects to be exhibited in the exhibition ''Renoir: The Body, The Senses,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Sterling and Francine Clark Art Institute, Williamstown, Massachusetts, from on or about June 8, 2019, until on or about September 22, 2019, at the Kimbell Art Museum, Fort Worth, Texas, from on or about October 27, 2019, until on or about January 26, 2020, 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 address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 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, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–09664 Filed 5–9–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10766]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Bauhaus Beginnings'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that the objects to be exhibited in the exhibition ''Bauhaus Beginnings,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Getty Research Institute at the Getty Center, Los Angeles, California, from on or about June 11, 2019, until on or about October 13, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 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, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–09653 Filed 5–9–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10763]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Treasures of Ancient Greece'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that the objects to be

exhibited in the exhibition ''Treasures of Ancient Greece,'' 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 Children's Museum of Indianapolis, Indianapolis, Indiana, from on or about June 15, 2019, until on or about January 5, 2020, 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 address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 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, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–09663 Filed 5–9–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10765]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Beyond Line: The Art of Korean Writing'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that the objects to be exhibited in the exhibition ''Beyond Line: The Art of Korean Writing,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Los Angeles County Museum of Art, Los Angeles, California, from on or about June 16, 2019, until on or about September 29, 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 address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 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, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–09652 Filed 5–9–19; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36283]

Allegheny Valley Railroad Company—Temporary Trackage Rights Exemption—Norfolk Southern Railway Company

Allegheny Valley Railroad Company (AVR) has filed a verified notice of exemption under 49 CFR 1180.2(d)(8) for acquisition of nonexclusive, temporary overhead trackage rights over a rail line of Norfolk Southern Railway Company (NSR) between CP Bloom, milepost PT 351.6 +/−, and CP Home, milepost PT 347.8 +/−, in Pittsburgh, Pa., a distance of approximately 3.8 miles.

AVR states that, pursuant to a written letter Agreement for Detour of Trains for Operating Convenience (Agreement), NSR has agreed to grant the specified temporary overhead trackage rights to AVR.[1] According to AVR, the purpose of the temporary trackage rights is to accommodate AVR's detour operations over NSR's line and permit continued rail service between several of AVR's rail lines while a trestle rehabilitation project is conducted on a nearby AVR rail line.[2]

The transaction may be consummated on or after May 25, 2019, the effective date of the exemption (30 days after the verified notice of exemption was filed). Under the Agreement, the temporary trackage rights will expire on September 27, 2019 (125 days after the exemption becomes effective).

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980), and any employees affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by May 17, 2019 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36283, must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on AVR's representative, Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

Board decisions and notices are available at *www.stb.gov.*

Decided: May 7, 2019.

By the Board, Allison C. Davis, Acting Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2019–09660 Filed 5–9–19; 8:45 am]

BILLING CODE 4915–01–P

[1] A copy of the Agreement, dated April 23, 2019, is included in the verified notice as Exhibit 2.

[2] AVR states that similar temporary trackage rights were authorized by the Board in 2016 in connection with the first phase of the trestle rehabilitation. *Allegheny Valley R.R.—Temp. Trackage Rights Exemption—Norfolk S. Ry.,* FD 36015 (STB served May 6, 2016).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA 2019–0356]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Changes in Permissible Stage 2 Airplane 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 **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 1, 2019 for information used to issue special flight authorizations for non-revenue transports and non-transport jet operations of Stage 2 airplanes at U.S. airports. Only a minimal amount of data is requested to identify the affected parties and determine whether the purpose for the flight is one of those enumerated by law. This collection is required under the Airport Noise and Capacity Act of 1990 and the FAA Modernization and Reform Act of 2012.

DATES: Written comments should be submitted by June 10, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

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: Sandy Liu by email at: *sandy.liu@faa.gov;* phone: 202–267–4748

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0652.

Title: Changes in Permissible Stage 2 Airplane Operations.

Form Numbers: FAA Form 1050–8.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 01, 2019 (84 FR 7161). This collection is required under the Airport Noise and Capacity Act of 1990 (as amended by Pub. L. 106–113) and the FAA Modernization and Reform Act of 2012. This information is used by the FAA to issue special flight authorizations for nonrevenue operations of transports and non-transport jet Stage 2 airplanes at U.S. airports. Only minimal amount of data is requested to identify the affected parties and determine whether the purpose for the flight is one of the ones enumerated in the law.

Respondents: Approximately 30 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 15 minutes.

Estimated Total Annual Burden: 7.5 hours.

Issued in Washington, DC, on May 7, 2019.

Sandy Liu,

Engineer, Noise Division, Office of Environment and Energy, Noise Division, AEE–100.

[FR Doc. 2019–09673 Filed 5–9–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2019–0128]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Notice of Landing Area Proposal

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 **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 4, 2019. The collection involves gathering information from airport sponsors about any establishment, construction, alteration, or change to the status or use of an airport. The FAA uses this information to conduct airport airspace analyses to understand the impact of proposed actions on existing and planned operating procedures, determine potential hazardous effects, and identify any mitigating measures needed to enhance safe air navigation. Additionally, the information updates the aeronautical charts and maps airports having emergency landing or landmark values.

DATES: Written comments should be submitted by June 10, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Raymond Zee by email at: *Raymond.Zee@faa.gov;* phone: 202–267–7669.

SUPPLEMENTARY INFORMATION:

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.

OMB Control Number: 2120–0036.

Title: Notice of Landing Area Proposal.

Form Numbers: FAA Form 7480–1.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period

soliciting comments on the following collection of information was published on March 4, 2019 (84 FR 7412). Title 14 Code of Federal Regulations Part 157, Notice of Construction, Alteration, Activation, and Deactivation of Airports, requires that each person who intends to establish, construct, deactivate, or change the status of an airport, runway, or taxiway notify the FAA of such activity. The FAA uses the information collected to determine the effect the proposed action will have on existing airports and on the safe and efficient use of airspace by aircraft, the effects on existing airspace or contemplated traffic patterns of neighboring airports, the effects on the existing airspace structure and projected programs of the FAA, and the effects that existing or proposed manmade objects (on file with the FAA) and natural objects within the affected area will have on the airport proposal. This information also updates aeronautical charts and maps airports having emergency landing or landmark values. The FAA collects this information via an online reporting tool available on the FAA website (FAA Form 7480–1).

Respondents: Approximately 350 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden: 350 hours.

Issued in Washington, DC, on May 6, 2019.

Raymond Zee,

Civil Engineer, Airport Engineering Division, Office of Airport Safety and Standards.

[FR Doc. 2019–09636 Filed 5–9–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FY 2019 Competitive Funding Opportunity: Public Transportation on Indian Reservations Program; Tribal Transit Program

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the availability of approximately $5 million in funding, subject to the availability of appropriations, for the Public Transportation on Indian Reservations Program (Tribal Transit Program). This notice is a national solicitation for project proposals and includes the selection criteria and program eligibility information for Fiscal Year (FY) 2019 projects. FTA may fund the program for more or less than the full year appropriation when made available, and may include other funding if available from other fiscal years toward project proposals received in response to this Notice of Funding Opportunity (NOFO).

This announcement is available on the FTA website at: *http://www.transit.dot.gov*. Additionally, a synopsis of the funding opportunity, FTA–2019–004–TPM–TRTR, will be posted in the FIND module of the government-wide electronic grants website at *http://www.grants.gov*. The program is located in the Catalog of Federal Domestic Assistance (CFDA) under 20.509.

DATES: Complete proposals for the Tribal Transit Program announced in this Notice must be submitted by 11:59 p.m. EDT on July 9, 2019. All proposals must be submitted electronically through the *GRANTS.GOV* APPLY function. Any applicant intending to apply should initiate the process of registering on the *GRANTS.GOV* site immediately to ensure completion of registration before the submission deadline. Instructions for applying can be found on FTA's website at *http://www.transit.dot.gov* and in the FIND module of *GRANTS.GOV*. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: Contact the appropriate FTA Regional Office at *http://www.transit.dot.gov* for proposal-specific information and issues. For general program information, contact Jasmine Clemons, Office of Program Management, (202) 366–2343, email: *jasmine.clemons@dot.gov*. A TDD is available at 1–800–877–8339 (TDD/FIRS).

SUPPLEMENTARY INFORMATION:

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Appendix A: Registering in SAM and *Grants.gov*

A. Program Description

The Tribal Transit Program is authorized by Federal Public Transit law at 49 U.S.C. 5311(c)(1)(A), contingent on full appropriations. The program authorizes grants ''under such terms and conditions as may be established by the Secretary'' to Indian tribes for any purpose eligible under FTA's Formula Grants for Rural Areas Program, 49 U.S.C. 5311. Tribes may apply for this funding directly.

The primary purpose of these competitively selected grants is to support planning, capital, and, in limited circumstances, operating assistance for tribal public transit services. Funds distributed to Indian tribes under the Tribal Transit Program should NOT replace or reduce funds that Indian tribes receive from States through FTA's Formula Grants for Rural Areas Program. Specific project eligibility under this competitive allocation is described in Section C of this notice.

B. Federal Award Information

Five million dollars is authorized for the Tribal Transit Program competitive allocation in FY 2019 to projects selected pursuant to the process described in the following sections. Federal awards under this competitive program will be in the form of grants. Additionally, there is a $25,000 cap on planning grant awards, and FTA has the discretion to cap capital and operating awards.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants include federally recognized Indian tribes or Alaska Native villages, groups, or communities as identified by the U.S. Department of the Interior (DOI) Bureau of Indian Affairs (BIA). As evidence of Federal recognition, an Indian tribe may submit a copy of the most up-to-date **Federal Register** notice published by BIA: Entities Recognized and Eligible to Receive Service from the United States Bureau of Indian Affairs. To be an eligible recipient, an Indian tribe must have the requisite legal, financial, and technical capabilities to receive and administer Federal funds under this program. Additionally, applicants must be located and provide service in a rural area with a population of 50,000 or less. A service area can include some portions of urban areas, as long as the tribal transit service begins in and serves rural areas. An applicant must be registered in the System for Award Management (SAM) database and maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by FTA.

2. Cost Sharing or Matching

There is a 90 percent Federal share for projects selected under the Tribal Transit Program competitive program, unless the Indian tribe can demonstrate

a financial hardship in its application. FTA is interested in the Indian tribe's financial commitment to the proposed project; thus, the proposal should include a description of the Indian tribe's financial commitment. Tribes may use any eligible local match under Chapter 53.

3. Eligible Projects

Eligible projects include public transportation planning and capital expenses. Operating projects are eligible in limited circumstances. In FY 2019, FTA will only consider operating assistance requests from tribes without existing transit service, or those tribes who received a Tribal Transit Program formula allocation of less than $20,000.

Public transportation includes regular, continuing shared-ride surface transportation services open to the public or open to a segment of the public defined by age, disability, or low income. FTA will award grants to eligible Indian tribes located in rural areas. Applicants may submit one proposal for each project or one proposal containing multiple projects. Specific types of projects include: Capital projects for start-ups, replacement, or expansion needs; operating assistance for start-ups; and planning projects up to $25,000. Indian tribes applying for capital replacement or expansion needs must demonstrate a sustainable source of operating funds for existing or expanded services.

D. Application and Submission Information

1. Address To Request Application Package

A complete proposal submission will consist of at least two files: (1) The SF 424 Mandatory form (downloaded from *GRANTS.GOV*); and (2) the Tribal Transit supplemental form found on the FTA website at *http://www.transit.dot.gov.* The Tribal Transit supplemental form provides guidance and a consistent format for applicants to respond to the criteria outlined in this NOFO.

2. Content and Form of Application Submission

(i) Proposal Submission

A complete proposal submission will consist of at least two files: (1) The SF 424 Mandatory form (downloaded from *GRANTS.GOV*); and (2) the Tribal Transit supplemental form found on the FTA website at *http://www.transit.dot.gov.* The applicant must place the supplemental form in the attachments section of the SF 424 Mandatory form. Applicants must use the supplemental form designated for the Tribal Transit Program and attach the form to their submission in *GRANTS.GOV* to complete the application process. A proposal submission may include additional supporting documentation as attachments. Within 48 hours after submitting an electronic application, the applicant should receive two email messages from *GRANTS.GOV*: (1) Confirmation of successful transmission to *GRANTS.GOV* and (2) confirmation of successful validation by *GRANTS.GOV*. If the applicant does not receive confirmations of successful validation or instead receives a notice of failed validation or incomplete materials, the applicant must address the reason(s) for the failed validation or incomplete materials, as described in the notice, and resubmit the proposal before the submission deadline. If making a resubmission for any reason, the applicant must include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

Complete instructions on the application process can be found at *http://www.transit.dot.gov.* Important: FTA urges applicants to submit their project proposals at least 72 hours prior to the due date to allow time to receive the validation message and to correct any problems that may have caused a rejection notification. FTA will not accept submissions after the stated submission deadline. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website at *http://www.GRANTS.GOV.* The deadline will not be extended due to scheduled maintenance or outages.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) Registration in the SAM is renewed annually; and (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions. Instructions on the *GRANTS.GOV* registration process are provided in the Appendix.

Applicants may submit one proposal for each project or one proposal containing multiple projects. Applicants submitting multiple projects in one proposal must be sure to clearly define each project by completing a supplemental form for each project. Additional supplemental forms must be added within the proposal by clicking the ''add project'' button in Section II of the supplemental form.

Information such as applicant name, Federal amount requested, description of areas served, and other information may be requested in varying degrees of detail on both the SF 424 form and supplemental form. Applicants must fill in all fields unless stated otherwise on the forms. Applicants should use both the ''Check Package for Errors'' and the ''Validate Form'' validation buttons on both forms to check all required fields on the forms, and ensure that the Federal and local amounts specified are consistent.

(ii) Application Content

The SF 424 Mandatory Form and the Supplemental Form will prompt applicants for the required information, including:

a. Name of federally recognized tribe and, if appropriate, the specific tribal agency submitting the application.

b. Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number if available. (*Note:* If selected, applicant will be required to provide DUNS number prior to grant award).

c. Contact information including: Contact name, title, address, fax and phone number, email address if available.

d. Description of public transportation services, including areas currently served by the tribe, if any.

e. Name of person(s) authorized to apply on applicant's behalf must accompany the proposal (attach a signed transmittal letter).

f. Complete Project Description: Indicate the category for which funding is requested (*i.e.,* project type: Capital, operating, or planning), and then indicate the project purpose (*i.e.,* start-up, expansion, or replacement). Describe the proposed project and what it will accomplish (*e.g.,* number and type of vehicles, routes, service area, schedules, type of services, fixed route or demand responsive, safety aspects), route miles (if fixed route), ridership numbers expected (actual if an existing system, estimated if a new system), major origins and destinations, population served, and whether the tribe provides the service directly, contracts for services, and note vehicle maintenance plans.

g. Project Timeline: Include significant milestones such as date of contract for purchase of vehicle(s), actual or expected delivery date of

vehicles; facility project phases (*e.g.,* NEPA compliance, design, construction); or dates for completion of planning studies. If applying for operational funding for new services, indicate the period of time that funds would be used to operate the system (*e.g.,* one year). This section should also include any needed timelines for tribal council project approvals, if applicable.

h. Budget: Provide a detailed budget for each proposed purpose, noting the Federal amount requested and any additional funds that will be used. An Indian tribe may use up to fifteen percent of a grant award for capital projects for specific project-related planning and administration, and the indirect cost rate may not exceed ten percent (if necessary, add as an attachment) of the total amount requested/awarded. Indian tribes must also provide their annual operating budget as an attachment or under the *Financial Commitment and Operating Capacity* section of the supplemental form.

i. Technical, Legal, Financial Capacity: Applicants must be able to demonstrate adequate technical, legal, and financial capacity to be considered for funding. Every proposal MUST describe this capacity to implement the proposed project.

1. *Technical Capacity:* Provide examples of management of other Federal projects, including previously funded FTA projects and/or similar types of projects for which funding is being requested. Describe the resources available to implement the proposed transit project.

2. *Legal Capacity:* Provide documentation or other evidence to demonstrate status as a federally recognized Indian tribe. Further, demonstrate evidence of an authorized representative with authority to bind the applicant and execute legal agreements with FTA. If applying for capital or operating funds, identify whether appropriate Federal or State operating authority exists.

3. *Financial Capacity:* Provide documentation or other evidence demonstrating current adequate financial systems to receive and manage a Federal grant. Fully describe: (1) All financial systems and controls; (2) other sources of funds currently managed; and (3) the long-term financial capacity to maintain the proposed or existing transit services.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) Be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. These requirements do not apply if the applicant: (1) Is an individual; (2) is excepted from the requirements under 2 CFR 25.110(b) or (c); or (3) has an exception approved by FTA under 2 CFR 25.110(d). FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. SAM registration takes approximately 3–5 business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps.

Step 1: Obtain DUNS Number

If requested by phone (1–866–705–5711), DUNS is provided immediately. If your organization does not have one, you will need to go to the Dun & Bradstreet website at *http://fedgov.dnb.com/webform* to obtain the number.

Step 2: Register with SAM

Registration may take three to five business days or up to two weeks. If you already have a Taxpayer Identification Number (TIN), your SAM registration will take three to five business days to process. If you are applying for an Employer Identification Number (EIN) please allow up to two weeks. Ensure that your organization is registered with the System for Award Management (SAM) at *https://www.sam.gov*. If your organization is not, an authorized official of your organization must register.

Step 3: Establish an Account in *Grants.gov*—Username & Password

Complete your Authorized Organization Representative (AOR) profile in *Grants.gov* and create your username and password. You will need to use your organization's DUNS Number to complete this step. See *https://apply07.grants.gov/apply/OrcRegister*.

Step 4: *Grants.gov*—AOR Authorization

The E-Business Point of Contact (E-Biz POC) at your organization must log in to *Grants.gov* to confirm an Authorized Organization Representative (AOR). Please note that there can be more than one AOR for your organization. In some cases, the E-Biz POC is also the AOR for an organization. * Time to complete depends on responsiveness of your E-Biz POC.

Step 5: Track or Status

At any time, you can track your AOR status by logging in with your username and password. Login as an Applicant (enter your username & password you obtained in Step 3).

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. EDT on July 9, 2019. Mail and fax submissions will not be accepted. Proposals submitted after the deadline will not be considered under any circumstance. Applications are time and date stamped by the FTA's Discretionary Grants System (DGS) upon successful submission.

5. Funding Restrictions

Funds must be used only for the specific purposes requested in the application. Funds under this NOFO cannot be used to reimburse projects for otherwise eligible expenses incurred prior to an FTA award under this program.

E. Application Review

1. Selection Criteria

FTA will use the following primary selection criteria when evaluating competing capital and operating assistance projects eligible under this program. Applications will be evaluated based on the quality and extent to which the following evaluation criteria are addressed.

(i.) Planning and Local/Regional Prioritization

Applications will be evaluated based on the degree to which the applicant: (1) Describes how the proposed project was developed; (2) demonstrates that a sound basis for the project exists; and (3) demonstrates that the applicant is ready to implement the project if funded. Information may vary depending upon how the planning process for the project was conducted and what is being requested. Planning and local/regional prioritization should:

a. Describe the planning document and/or the planning process conducted to identify the proposed project;

b. Provide a detailed project description, including the proposed service, vehicle and facility needs, and other pertinent characteristics of the proposed or existing service implementation;

c. Identify existing transportation services in and near the proposed service area, and document in detail whether the proposed project will provide opportunities to coordinate service with existing transit services, including human service agencies, intercity bus services, or other public transit providers;

d. Discuss the level of support by the community and/or tribal government for the proposed project;

e. Describe how the mobility and client-access needs of tribal human services agencies were considered in the planning process;

f. Describe what opportunities for public participation were provided in the planning process and how the proposed transit service or existing service has been coordinated with transportation provided for the clients of human services agencies, with intercity bus transportation in the area, or with any other rural public transit providers;

g. Describe how the proposed service complements rather than duplicates any currently available services;

h. Describe the implementation schedule for the proposed project, including time period, staffing, and procurement; and

i. Describe any other planning or coordination efforts not mentioned above.

(ii.) Project Readiness

Applications will be evaluated on the degree to which the applicant describes readiness to implement the project. The project readiness factor involves assessing whether:

a. The project is a Categorical Exclusion (CE) or the required environmental work has been initiated or completed, for construction projects requiring an Environmental Assessment (EA) or Environmental Impact Statement (EIS) under, among others, the National Environmental Policy Act of 1969, as Amended;

b. Project implementation plans are complete, including initial design of facilities projects;

c. Project funds can be obligated and the project can be implemented quickly, if selected; and

d. The applicant demonstrates the ability to carry out the proposed project successfully.

(iii.) Demonstration of Need

Applications will be evaluated based on the degree to which the applicant identifies the need for transit resources. In addition to project-specific criteria, FTA will consider the project's impact on service delivery and whether the project represents a one-time or periodic need that cannot reasonably be funded from FTA program formula allocations or State and/or local resources. FTA will evaluate how the proposal demonstrates the transit needs of the Indian tribe as well as how the proposed transit improvements or the new service will address identified transit needs. Proposals should include information such as destinations and services not currently accessible by transit; needs for access to jobs or health care; safety enhancements; special needs of elders or individuals with disabilities; behavioral health care needs of youth; income-based community needs; or other mobility needs. If an applicant received a planning grant in previous fiscal years, the proposal should indicate the status of the planning study and how the proposed project relates to that study.

Applicants applying for capital expansion or replacement projects should also address the following factors in their proposal. If the proposal is for capital funding associated with an expansion or expanded service, the applicant should describe how current or growing demand for the service necessitates the expansion (and therefore, more capital) and/or the degree to how the project is addressing a current capacity constraint. Capital replacement projects should include information about the age, condition, and performance of the asset to be replaced by the proposed project and/or how the replacement may be necessary to maintain the transit system in a state of good repair.

(iv.) Demonstration of Benefits

Applications will be evaluated based on the degree to which the applicant identifies expected or, in the case of existing service, achieved project benefits. FTA is particularly interested in how these investments will improve the quality of life for the tribe and surrounding communities in which it is located. Applicants should describe how the transportation service or capital investment will provide greater access to employment opportunities, educational centers, healthcare, or other needs that impact the quality of life for the community, as described in the program purpose above. Possible examples include: Increased or sustained ridership and daily trips; improved service; elimination of gaps in service; improved operations and coordination; increased reliability; and health care, education, and economic benefits to the community. Benefits can be demonstrated by identifying the population of tribal members and non-tribal members in the proposed project service area and estimating the number of daily one-way trips the proposed transit service will provide or the actual number of individual riders served. Applicants are encouraged to consider qualitative and quantitative benefits to the Indian tribe and to the surrounding communities that are meaningful to them.

Using the information provided under this criterion, FTA will rate proposals based on the quality and extent to which they discuss the following four factors:

a. The project's ability to improve transit efficiency or increase ridership;

b. Whether the project will improve or maintain mobility, or eliminate gaps in service for the Indian tribe;

c. Whether the project will improve or maintain access to important destinations and services;

d. Any other qualitative benefits, such as greater access to jobs, education, and health care services.

(v.) Financial Commitment and Operating Capacity

Applications must identify the source of local match (10 percent is required for all operating and capital projects), and any other funding sources used by the Indian tribe to support proposed transit services, including human service transportation funding, the Federal Highway Administration's Tribal Transportation Program funding, or other FTA programs. If requesting that FTA waive the local match based on financial hardship, the applicant must submit budgets and sources of other revenue to demonstrate hardship. FTA will review this information and notify a tribe at the time of award if the waiver is approved. If applicable, the applicant also should describe how prior year Tribal Transit Program funds were spent to date to support the service. Additionally, Indian tribes applying to operate new services should provide a sustainable funding plan that demonstrates how it intends to maintain operations.

In evaluating proposals, FTA will consider any other resources the Indian tribe will contribute to the project, including in-kind contributions, commitments of support from local businesses, donations of land or equipment, and human resources. The proposal should describe to what extent the new project or funding for existing service leverages other funding. Based upon the information provided, the proposals will be rated on the extent to which the proposal demonstrates that:

a. Tribal Transit Program funding does not replace existing funding;

b. The Indian tribe will provide non-financial support to the project;

c. The Indian tribe is able to demonstrate a sustainable funding plan; and

d. Project funds are used in coordination with other services for efficient utilization of funds.

(vi.) Evaluation Criteria for Planning Proposals

For planning grants, the proposal must describe the need for and a general scope of the proposed study. Applications will be evaluated based on the degree to which the applicant addresses the following:

a. The tribe's long-term commitment to transit; and

b. The method used to implement the proposed study and/or further tribal transit.

2. Review and Selection Process

An FTA technical evaluation committee will review proposals under the project evaluation criteria. Members of the technical evaluation committee and other involved FTA staff reserve the right to screen the applications, and seek clarification about any statement in an application. After consideration of the findings of the technical evaluation committee, the FTA Administrator will determine the final selection and amount of funding for each project. Geographic diversity and the applicant's receipt and management of other Federal transit funds may be considered in FTA's award decisions. After applying the above preferences, the FTA Administrator will consider the following key Departmental objectives:

(A) Supporting economic vitality at the national and regional level;

(B) Utilizing alternative funding sources and innovative financing models to attract non-Federal sources of infrastructure investment;

(C) Accounting for the life-cycle costs of the project to promote the state of good repair;

(D) Using innovative approaches to improve safety and expedite project delivery; and,

(E) Holding grant recipients accountable for their performance and achieving specific, measurable outcomes identified by grant applicants.

Prior to making an award, FTA is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIIS). An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

F. Federal Award Administration

1. Federal Award Notice

FTA will publish a list of the selected projects, including Federal dollar amounts and award recipients, on FTA's website. Project recipients should contact their FTA Regional Offices and tribal liaison for information about setting up grants in FTA's Transit Award Management System (TrAMS).

2. Award Administration

Successful proposals will be awarded through FTA's TrAMS as grant agreements. The appropriate FTA Regional Office and tribal liaison will manage project agreements.

3. Administrative and National Policy Requirements

Except as otherwise provided in this NOFO, Tribal Transit Program grants are subject to the requirements of 49 U.S.C. 5311(c)(1) as described in the latest FTA Circular 9040 for the Formula Grants for Rural Areas Program.

4. Reporting

The post-award reporting requirements include submission of the Federal Financial Report (FFR) and Milestone Progress Report in TrAMS, and FTA's National Transit Database (NTD) reporting as appropriate (see FTA Circular 9040). Reports to TrAMS and NTD are due annually.

G. Federal Awarding Agency Contacts

For further information concerning this notice, please contact Jasmine Clemons, Office of Program Management, (202) 366–2343, email: *jasmine.clemons@dot.gov*. A TDD is available at 1–800–877–8339 (TDD/FIRS).

H. Other Information

This program is not subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' FTA will consider applications for funding only from eligible recipients for eligible projects listed in Section C of this Notice. Due to funding limitations, applicants that are selected for funding may receive less than the amount requested.

Additionally, to assist tribes with understanding requirements under the Tribal Transit Program, FTA has conducted Tribal Transit Technical Assistance Workshops and will continue those efforts in FY 2019. FTA has expanded its technical assistance to tribes receiving funds under this program. Through the Tribal Transit Technical Assistance Assessments Initiative, FTA collaborates with Tribal Transit Leaders to review processes and identify areas in need of improvement, and then assists to offer solutions to address these needs—all in a supportive and mutually beneficial manner that results in technical assistance. FTA has completed over fifty assessments to date and expects to conduct fifteen assessments in FY 2019. These assessments include discussions of compliance areas pursuant to the Master Agreement, a site visit, promising practices reviews, and technical assistance from FTA and its contractors.

These workshops and assessments have received exemplary feedback from Tribal Transit Leaders and provided FTA with invaluable opportunities to learn more about Tribal Transit Leaders' perspectives and better honor the sovereignty of tribal nations.

FTA will post information about upcoming workshops to its website and will disseminate information about the assessments through its regional offices. Contact information for FTA's regional offices can be found on FTA's website at *www.transit.dot.gov*. Applicants may also receive technical assistance by contacting their FTA regional Tribal Liaison.

A list of Tribal Liaisons is available on FTA's website at *www.transit.dot.gov*.

K. Jane Williams,

Acting Administrator.

Appendix A

Registering in SAM and *Grants.gov*

Registration in Brief: Registration takes approximately three to five business days; please allow four weeks for completion of all steps.

In order to apply for a grant, you and/or your organization must first complete the registration process in *Grants.gov*. The registration process for an Organization or an Individual can take between three to five business days or as long as four weeks if all steps are not completed in a timely manner. So please register in *Grants.gov* early.

The *Grants.gov* registration process ensures that applicants for Federal funds have the basic prerequisites to apply for and to receive Federal funds. Applicants for FTA competitive funds must:

- Have a valid DUNS number
- Have a current registration in SAM (formerly CCR)
- Register and apply in *Grants.gov*

The required registration steps are described in greater detail on the *Grants.gov* website. The following is a link to a helpful checklist and explanations published by *Grants.gov* to assist applicants: Organization

Registration Checklist. If you have not recently applied for Federal funds, we recommend that you initiate your search, registration, and application process with *Grants.gov*. Visiting the *Grants.gov* site will inform you of how to apply for grant opportunities, as well as assist you in linking to the other required registrations, *i.e.,* Dun & Bradstreet to obtain a DUNS Number, and System for Award Management (SAM).

Summary of steps (these steps are available in *Grants.gov* during registration):

Step 1: Obtain DUNS Number

Same day. If requested by phone (1–866–705–5711), DUNS is provided immediately. If your organization does not have one, you will need to go to the Dun & Bradstreet website at *http://fedgov.dnb.com/webform* to obtain the number.

Step 2: Register With SAM

Three to five business days or up to two weeks. If you already have a Taxpayer Identification Number (TIN), your SAM registration will take three to five business days to process. If you are applying for an Employer Identification Number (EIN) please allow up to two weeks. Ensure that your organization is registered with the System for Award Management (SAM) at *https://www.sam.gov*. If your organization is not, an authorized official of your organization must register.

Step 3: Establish an Account in Grants.gov—Username & Password

Same day. Complete your Authorized Organization Representative (AOR) profile on *Grants.gov* and create your username and password. You will need to use your organization's DUNS Number to complete this step. See *https://apply07.grants.gov/apply/OrcRegister*.

Step 4: Grants.gov—AOR Authorization

*Same day. The E-Business Point of Contact (E-Biz POC) at your organization must login to *Grants.gov* to confirm you as an Authorized Organization Representative (AOR). Please note that there can be more than one AOR for your organization. In some cases, the E-Biz POC is also the AOR for an organization. * Time to complete depends on responsiveness of your E-Biz POC.

* *Please Note: Grants.gov* gives you the option of registering as an ''individual'' or as an ''Organization.'' If you register in *Grants.gov* as an as an ''Individual,'' your ''Organization'' will not be allowed to use the *Grants.gov* username and password. To apply for grants as an Organization, you must register as an Organization and use that specific username and password issued during the ''Organization'' registration process.

[FR Doc. 2019–09332 Filed 5–9–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2018–0114; Notice No. 2019–04]

Hazardous Materials: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requests (ICRs) discussed below will be forwarded to the Office of Management and Budget (OMB) for renewal and extension. These ICRs describe the nature of the information collections and their expected burdens. A **Federal Register** notice with a 60-day comment period soliciting comments on these ICRs was published in the **Federal Register** on February 25, 2019 under Docket No. PHMSA–2018–0114 (Notice No. 2018–24). PHMSA received two comments in response to the February 25, 2019 notice. One comment from Bruce Grimm was supportive of PHMSA continuing to collect information related to subsidiary hazards under OMB control number 2137–0613. The other comment was outside the scope of this notice.

DATES: Interested persons are invited to submit comments on, or before June 10, 2019.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, by mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOT–PHMSA, 725 17th Street NW, Washington, DC 20503, by fax, 202–395–5806, or by email, to *OIRA_Submission@omb.eop.gov.* Comments should refer to the information collection by title and/or OMB Control Number.

We invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the Department's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Steven Andrews or Shelby Geller, Standards and Rulemaking Division (PHH–10), U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, 1200 New Jersey Avenue SE, East Building, 2nd Floor, Washington, DC 20590–0001, Telephone (202) 366–8553.

SUPPLEMENTARY INFORMATION: Section 1320.8 (d), Title 5, Code of Federal Regulations requires Federal agencies to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collection requests that PHMSA will be submitting to OMB for renewal and extension. These information collections are contained in 49 CFR parts 110, 172, and 173 of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). PHMSA has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in proposed or final rules published since the information collections were last approved. The following information is provided for each information collection: (1) Title of the information collection, including former title if a change is being made; (2) OMB Control Number; (3) abstract of the information collection activity; (4) description of affected persons; (5) estimate of total annual reporting and recordkeeping burden; and (6) frequency of collection. PHMSA will request a three-year term of approval for each information collection activity and, when approved by OMB, publish notice of the approvals in the **Federal Register**.

PHMSA requests comments on the following information collections:

Title: Radioactive (RAM) Transportation Requirements.

OMB Control Number: 2137–0510.

Summary: This information collection consolidates and describes the information collection provisions in the HMR involving the transportation of radioactive materials in commerce. Information collection requirements for RAM include: Documenting testing and engineering evaluations for packages, documentation for DOT 7A packages, revalidation of foreign competent authority certifications, providing specific written instruction of exclusive use shipment controls, providing

written instructions for exclusive use shipment controls, obtaining U.S. competent authority for package design, registering with U.S. competent authority as user of a package, and request for a U.S. competent authority for special form. The following information collections and their burdens are associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Document Test and Engineering Evaluation or Comparative Data for Packaging—Reporting	50	100	40	4,000
DOT Specification 7A Package Documentation—Reporting	50	100	80	8,000
DOT Specification 7A Package Documentation—Recordkeeping	50	500	0.0833	41.67
Revalidation of Foreign Competent Authority Certification—Reporting	25	25	80	2,000
Offeror Providing Specific Written Instruction of Exclusive Use Shipment Controls to the Carrier—Reporting	100	2,000	0.5	1,000
Offeror Obtaining U.S. Competent Authority for Package Design—Reporting	10	40	2	80
Register with U.S. Competent Authority as User of a Package—Reporting	25	50	0.5	25
Request for a U.S. Competent Authority as Required by the IAEA Regulations for Special Form—Reporting	10	100	2	200

Affected Public: Shippers and carriers of radioactive materials in commerce.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 320.

Total Annual Responses: 2,915.

Total Annual Burden Hours: 15,347.

Frequency of Collection: On occasion.

Title: Hazardous Materials Public Sector Training and Planning Grants.

OMB Control Number: 2137–0586.

Summary: 49 CFR part 110 sets forth the procedures for reimbursable grants for planning and training in support of the emergency preparedness efforts of States, Indian tribes, and local communities to manage hazardous materials emergencies, particularly those involving transportation. Sections in this part address information collection and recordkeeping with regard to applying for grants, monitoring expenditures, and reporting and requesting modifications. The following information collection and burden is associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Hours per response	Total annual burden hours
Hazardous Materials Grants Applications	62	62	83.23	5,160

Affected Public: State and local governments, Indian tribes.

Annual Reporting and Recordkeeping Burden:

Annual Respondents: 62.

Annual Responses: 62.

Annual Burden Hours: 5,160.

Frequency of Collection: On occasion.

Title: Subsidiary Hazard Class and Number/Type of Packagings.

OMB Control Number: 2137–0613.

Summary: The HMR require that shipping papers and emergency response information accompany each shipment of hazardous materials in commerce. In addition to the basic shipping description information, we also require the subsidiary hazard class or subsidiary division number(s) to be entered in parentheses following the primary hazard class or division number on shipping papers. This requirement was originally required only by transportation by vessel. However, the lack of such a requirement posed problems for motor carriers with regard to complying with segregation, separation, and placarding requirements, as well as posing a safety hazard. For example, in the event the motor vehicle becomes involved in an accident, when the hazardous materials being transported include a subsidiary hazard such as ''dangerous when wet'' or a subsidiary hazard requiring more stringent requirements than the primary hazard, there is no indication of the subsidiary hazards on the shipping papers and no indication of the subsidiary risks on placards. Under circumstances such as motor vehicles being loaded at a dock, labels are not enough to alert hazardous materials employees loading the vehicles, nor are they enough to alert emergency responders of the subsidiary risks contained on the vehicles. Therefore, we require the subsidiary hazard class or subsidiary division number(s) to be entered on the shipping paper, for purposes of enhancing safety and international harmonization.

Shipping papers serve as a principal means of identifying hazardous materials during transportation emergencies. Firefighters, police, and other emergency response personnel are trained to obtain the DOT shipping papers and emergency response information when responding to hazardous materials transportation emergencies. The availability of accurate information concerning hazardous materials being transported significantly improves response efforts in these types of emergencies. The additional information would aid emergency responders by more clearly identifying the hazard.

The following information collection and burden is associated with this OMB Control Number:

Information collection	Respondents	Total annual responses	Seconds per response	Total annual burden hours
Subsidiary Hazard Class on Shipping Papers	260,000	43,810,000	2	24,339

Affected Public: Shippers and carriers of hazardous materials in commerce.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 260,000.

Total Annual Responses: 43,810,000.

Total Annual Burden Hours: 24,339.

Frequency of Collection: On occasion.

Issued in Washington, DC, on May 6, 2019.

William S. Schoonover,

Associate Administrator of Hazard Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2019–09624 Filed 5–9–19; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request; Bank Secrecy Act/Money Laundering Risk Assessment

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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.

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning its information collection entitled, ''Bank Secrecy Act/Money Laundering Risk Assessment,'' also known as the Money Laundering Risk (MLR) System. DATES: Comments must be submitted by July 9, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, OMB Control No. 1557–0231, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0231'' in your comment. In general, the OCC publishes comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection [1] by any of the following methods:

- Viewing Comments Electronically: Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0231'' or ''Bank Secrecy Act/Money Laundering Risk Assessment.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- Viewing Comments Personally: You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 874–5090, or for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA, federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include questions posed to agencies, instrumentalities, or employees of the United States, if the results are to be used for general statistical purposes, that is, if the results are to be used for statistical compilations of general public interest, including compilations showing the status or implementation of federal activities and programs. Section 3506(c)(2)(A) of the PRA requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or revision of an existing collection of information, before submitting the collection to OMB for approval. In compliance with the PRA, the OCC is publishing notice of the proposed extension with revision of the collection of information set forth in this document.

Title: Bank Secrecy Act/Money Laundering Risk Assessment.

OMB Control No: 1557–0231.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Description: The MLR System enhances the ability of examiners and bank management to identify and evaluate Bank Secrecy Act/Money Laundering and Office of Foreign Asset Control (OFAC) sanctions risks associated with banks' products, services, customers, and locations. As new products and services are introduced, existing products and services change, and banks expand through mergers and acquisitions, banks' evaluation of money laundering and terrorist financing risks should evolve as well. Consequently, the MLR risk assessment is an important tool for the OCC's Bank Secrecy Act/Anti-Money Laundering and OFAC supervision activities because it allows the agency to better identify those institutions, and areas within institutions, that pose heightened risk and allocate examination resources accordingly. This risk assessment is critical in protecting U.S. financial institutions of all sizes from potential abuse from money laundering and terrorist financing. An appropriate risk assessment allows applicable control to be effectively implemented for the lines of business, products, or entities that

[1] Following the close of the 60-day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

would elevate Bank Secrecy Act/Money Laundering and OFAC compliance risks.

We will collect MLR information for community banks supervised by the OCC.

The format of OCC's annual Risk Summary Form (RSF) is fully automated, making data entry quick and efficient and providing an electronic record for all parties.

The OCC estimates the burden of this collection of information as follows:

Burden Estimates:

Community bank population:

Estimated Number of Respondents: 1,088.

Estimated Number of Responses: 1,088.

Frequency of Response: Annually.

Estimated Annual Burden: 6,528 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 6, 2019.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2019–09614 Filed 5–9–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0564]

Agency Information Collection Activity Under OMB Review: Direct Deposit Enrollment; International Direct Deposit Enrollment

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: June 10, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer, 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0564'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, (202) 421–1354.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Direct Deposit Enrollment (24–0296); International Direct Deposit Enrollment (24–0296a).

OMB Control Number: 2900–0564.

Type of Review: Reinstatement with change of a previously approved collection.

Abstract: The information collected on these forms will be used to enroll VA benefit recipients in the electronic funds transfer (EFT) program.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 84 FR 7183 on March 1, 2019, page 7184.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,250 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 5,000.

By direction of the Secretary.

Danny S. Green,

VA Interim Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2019–09273 Filed 5–9–19; 8:45 am]

BILLING CODE 8320–01–P

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Part II

Department of Energy

10 CFR Part 431

Energy Conservation Program: Test Procedure for Distribution Transformers; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2017–BT–TP–0055]

RIN 1904–AB39

Energy Conservation Program: Test Procedure for Distribution Transformers

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

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The U.S. Department of Energy (''DOE'') proposes clarifying amendments to the test procedure for distribution transformers to revise and add definitions of certain terms, to incorporate revisions based on the latest versions of relevant Institute of Electrical and Electronics Engineers (IEEE) industry standards, and to specify the basis for voluntary representations at additional per-unit loads (PULs) and additional reference temperatures. The proposals in this NOPR are minor revisions that do not significantly change the test procedure. Therefore, none of the revisions would pose undue burden on manufacturers. DOE is seeking comment from interested parties on the proposal.

DATES: DOE will accept comments, data, and information regarding this notice of proposed rulemaking (NOPR) no later than July 9, 2019. See section V, ''Public Participation,'' for details.

ADDRESSES: Any comments submitted must identify the Test Procedure NOPR for Distribution Transformers and provide docket number EERE–2017–BT–TP–0055 and/or regulatory information number (RIN) 1904–AB39. Comments may be submitted using any of the following methods:

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

(2) *Email: DistributionTransformers2017TP0055@EE.DOE.Gov*. Include the docket number and/or RIN in the subject line of the message.

(3) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

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

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting written comments and additional information on the rulemaking process, see section V of this document (Public Participation).

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *http://www.regulations.gov*. All documents in the docket are listed in the *http://www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at *https://www.regulations.gov/docket?D=EERE-2017-BT-TP-0055*. The docket web page will contain simple instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–1777. Email: *sarah.butler@hq.doe.gov*.

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov*.

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I. Authority and Background

DOE is authorized to establish and amend energy conservation standards

and test procedures for certain industrial equipment, including distribution transformers. (42 U.S.C. 6317(a)) The current DOE test procedures for distribution transformers appear at title 10 of the Code of Federal Regulations (''CFR'') 431.193 and appendix A to subpart K of 10 CFR part 431 (herein referenced as ''appendix A''). The following sections discuss DOE's authority to establish and amend test procedures for distribution transformers, as well as relevant background information regarding DOE's consideration of test procedures for this equipment.

A. Authority

The Energy Policy and Conservation Act of 1975, as amended (''EPCA'') [1] among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [2] of EPCA, added by Public Law 95–619, Title IV, § 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. This equipment includes distribution transformers, the subject of this NOPR. (42 U.S.C. 6317(a))

Under EPCA, DOE's energy conservation program consists of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA for distribution transformers include definitions (42 U.S.C. 6291; 42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6295; 42 U.S.C. 6317), test procedures (42 U.S.C. 6293; 42 U.S.C. 6314), labeling provisions (42 U.S.C. 6294; 42 U.S.C. 6315), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316)

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for (1) certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6296), and (2) making representations about the efficiency of those products (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the products comply with any relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA provides in relevant part that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which measure energy efficiency, energy use and estimated annual operating cost of a covered equipment during a representative average use cycle or period of use and not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2))

In addition, if DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6314(b)) EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered equipment, including distribution transformers, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and to be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle. (42 U.S.C. 6314(a)(1)) If the Secretary determines that a test procedure amendment is warranted, the Secretary must publish proposed test procedures in the **Federal Register**, and afford interested persons an opportunity (of not less than 45 days' duration) to present oral and written data, views, and arguments on the proposed test procedures. (42 U.S.C. 6314(b)) DOE is publishing this NOPR to satisfy the 7-year review requirement specified in EPCA. (42 U.S.C. 6314(a)(1)(A))

With respect to distribution transformers, EPCA states that the test procedures for distribution transformers shall be based on the ''Standard Test Method for Measuring the Energy Consumption of Distribution Transformers'' prescribed by the National Electrical Manufacturers Association (NEMA TP 2–1998). (42 U.S.C. 6293(b)(10)(A)) Further, DOE may review and revise the DOE test procedure. (42 U.S.C. 6293(b)(10)(B))

B. Background

DOE's existing test procedure for distribution transformers appears at 10 CFR 431.193 and appendix A. EPCA directed DOE to prescribe testing procedures for those ''distribution transformers'' for which DOE determines that energy conservation standards ''would be technologically feasible and economically justified, and would result in significant energy savings.'' (42 U.S.C. 6317(a)(1)) EPCA states that the testing procedures for distribution transformers shall be based on the ''Standard Test Method for Measuring the Energy Consumption of Distribution Transformers'' prescribed by the National Electrical Manufacturers Association (NEMA TP 2–1998). (42 U.S.C. 6293(b)(10)(A)) Upon establishment of the required test procedures, EPCA required DOE to establish standards for those distribution transformers for which test procedures were prescribed. (42 U.S.C. 6317(a)(2)) DOE has established standards for distribution transformers at 10 CFR 431.196. 70 FR 60407 (October 18, 2005); 78 FR 23336 (Apr. 18, 2013).

Accordingly, DOE prescribed the test procedure for distribution transformers on April 27, 2006 (hereafter ''April 2006 TP final rule''). 71 FR 24972. In an April 2013 final rule amending the standards for distribution transformers (hereafter ''April 2013 ECS final rule''), DOE determined that the test procedures did not require amendment at that time, concluding that the test procedure as established in the April 2006 TP final rule was reasonably designed to produce test results that reflect energy efficiency and energy use, as required by 42 U.S.C. 6314(a)(2). 78 FR 23336, 23347–48 (April 18, 2013).

On September 22, 2017, DOE published a request for information (RFI) to collect data and information to inform its decision in satisfaction with the 7-year review requirement specified in EPCA (hereafter ''September 2017 TP RFI''). 82 FR 44347. In response to the September 2017 TP RFI, National Electrical Manufacturers Association (NEMA) requested an extension of the comment period. (NEMA, No. 4 at p. 1) DOE published a notice on October 31, 2017, reopening the public comment period until November 6, 2017. 82 FR 50324.

In this document, DOE is proposing amendments to the test procedure for distribution transformers. DOE also addresses the comments received in response to the September 2017 TP RFI.

[1] All references to EPCA refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (October 23, 2018).

[2] For editorial purposes, upon codification into the U.S. Code, Part C was redesignated as Part A–1.

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE proposes to update 10 CFR 429.47, 431.192, 431.193, 431.196 and appendix A as follows:

(1) Explicitly specify that the test procedure is applicable only to distribution transformers that are subject to energy conservation standards,

(2) Include new definitions for ''per-unit load,'' ''terminal'' and ''auxiliary device,'' and updated definitions for ''low-voltage dry-type distribution transformer'' and ''reference temperature,''

(3) Reflect certain revisions from the latest version [3] of the IEEE standards on which the DOE test procedure is based,

(4) Incorporate other clarifying revisions based on review of the DOE test procedure,

(5) Require manufacturers to use the DOE test procedure to make voluntary (optional) representations at additional PULs and reference temperatures,[4] and

(6) Centralize the per-unit load and reference temperature specifications for certification to energy conservation standards and for voluntary representations.

Table II.1 summarizes the proposed test procedure amendments compared to the current test procedure, as well as the reason for the change.

TABLE II.1—SYNOPSIS OF THE PROPOSED TEST PROCEDURE

Current DOE TP	Proposed TP	Attribution
Current test procedure does not specify scope	States explicitly that the scope of the test procedure is limited to the scope of the energy conservation standards (10 CFR 431.196). DTs not subject to ECSs are not subject to the TP.	Clarification added by DOE.
Per-unit load (PUL) is referred to in the DOE TP as ''percent load,'' ''percent of nameplate-rated load,'' ''percent of the rated load,'' or ''per unit load level''.	Adds new definition for ''per-unit load'' (PUL) and consolidates all the terms in subpart K of 10 CFR part 431 to only ''per-unit load''.	Improves consistency and readability of test procedure.
Does not define ''Per-unit load,'' ''Terminal'' and ''Auxiliary device,'' which are used in the current TP.	Adds new definitions for ''Per-unit load,'' ''Terminal'' and ''Auxiliary device'' based on industry IEEE standards and other research. (10 CFR 431.192).	Reflects industry standard definition (terminal) and clarification added by DOE (PUL and auxiliary device).
Follows four IEEE industry standards, which contain general electric and mechanical requirements and methods for performing tests: (1) C57.12.00-*2000*. (2) C57.12.01-*1998*. (3) C57.12.90-*1999*. (4) C57.12.91-*2001*.	Proposes amendments that reflect the *latest version* of the four IEEE industry standards: (1) C57.12.00-*2015*. (2) C57.12.01-*2015*. (3) C57.12.90-*2015*. (4) C57.12.91-*2011*. (Throughout appendix A to subpart K of part 431)	Reflects industry standard updates.
Requires reporting performance at the rated frequency; however, the rated frequency is not explicitly stated.	States explicitly that all testing under the DOE test procedure is to occur only at 60 Hz, consistent with the frequency used by the US electric transmission and distribution system. (Appendix A, sections 3.1(c), 4.1).	Update to reflect industry standards.
Requires determining winding resistance but does not specify whether the polarity of the core magnetization should be kept constant as measurements are made.	Specifies that the polarity of the core magnetization be kept constant during all resistance readings, consistent with industry test method. (Appendix A, section 3.4.1(f)).	Update to reflect industry standards.
Requires the measurement of load and no-load loss, without explicitly specifying the connection locations for measurements.	Specifies explicitly that load and no-load loss measurements are required to be taken only at the transformer terminals. (Appendix A, section 3.4.1(g)–(i)).	Update to reflect industry standards.
Testing with a sinusoidal waveform explicitly specified only for transformers designed for harmonic currents.	Specifies that *all* transformers must be tested using a sinusoidal waveform (not just those designed for harmonic current). (Appendix A, section 4.1).	Update to reflect industry practice.
Requires that efficiency must be determined at a single test per-unit load (PUL) of 50 percent for both liquid-immersed and MVDT distribution transformers, and at a single test PUL of 35 percent for LVDT distribution transformers.	Permits *voluntary* representations of efficiency, load loss and no-load loss at additional PULs and/or reference temperature, using the DOE TP. Does not require certification to DOE of any voluntary representations. (Appendix A, new section 7).	Response to industry comment.
Specifies PUL and reference temperature specifications for certification to energy conservation standards in multiple locations throughout appendix A.	Centralizes the PUL and reference temperature specifications, both for the certification to energy conservation standards and for use with a voluntary representation. (Appendix A, new sections 2.1 and 2.2).	Improves readability of test procedure.

[3] 42 U.S.C. 6314(d) generally requires that 180 days after a test procedure rule applicable to any covered equipment is prescribed under this section, a manufacturer who makes a representation of energy consumption of such equipment must test in accordance with the applicable test procedure. Any voluntary (optional) representations at additional PULs and/or temperatures would be required to fairly disclose the results of such testing.

[4] The existing test procedure already includes equations for producing representations at additional PULs and reference temperatures.

DOE has tentatively determined that the proposed updates would not change measured values used for certifying compliance with existing energy conservation standards for distribution transformers or pose undue test burden. DOE's proposed actions are addressed in detail in section III of this document.

III. Discussion

The following sections focus on certain aspects of DOE's test procedure, including rulemaking process, scope and definitions, revisions based on industry standards, per-unit load (PUL) testing requirements, purchasing decision, load growth, temperature correction, multiple voltage capabilities, other test procedure issues and updates, sampling, representations and alternate efficiency determination method (AEDM), test procedure costs and harmonization, and compliance date and waivers. The proposals in this NOPR are minor revisions that do not significantly change the test procedure. Therefore, none of the revisions would increase burden on manufacturers. Relevant comments received in response to the September 2017 TP RFI are addressed in the appropriate sections in the following discussion. Table III.1 includes the list of stakeholders that submitted comments.

TABLE III.1—LIST OF STAKEHOLDERS THAT SUBMITTED COMMENTS *

Stakeholder group	Stakeholder listing (and abbreviation used in this NOPR)
Efficiency Advocates	American Council for an Energy-Efficiency Economy and Appliance Standards Awareness Program (ACEEE & ASAP).
Manufacturers	Howard Industries, NEMA, Powersmiths International Corp. (Powersmiths), Prolec-GE.
Utilities	American Public Power Association (APPA), Edison Electric Institute (EEI), National Rural Electric Cooperative Association (NRECA), Pacific Gas and Electric Company, Southern California Gas Company, Southern California Edison and San Diego Gas & Electric Company (hereafter called California Investor Owner Utilities, or CA IOUs).
Steel Producers	AK Steel, Metglas.
Others	HVOLT Inc., Babanna Suresh (Suresh), Mikro-Kod Consulting (MKC).

* DOE received other comments from anonymous submitters that were unrelated to the Distribution Transformer Test Procedure and are therefore not addressed in this NOPR but are available for review on the docket. The docket web page can be found at *https://www.regulations.gov/docket?D=EERE-2017-BT-TP-0055*.

A. Rulemaking Process

In response to the September 2017 TP RFI, DOE received several comments regarding the rulemaking process.

EEI and APPA stated that DOE should complete work on the test procedure before issuing any advanced notice of proposed rulemaking (ANOPR) or ''no new standard'' determination for the energy conservation standards. (EEI, No. 16 at p. 2; APPA, No. 24 at p. 1) DOE notes that for rulemakings related to covered equipment, it generally seeks to follow the process outlined in 10 CFR part 430 subpart C appendix A, *Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products* (hereafter the ''Process Improvement Rule''). The Process Improvement Rule provides that, when appropriate and otherwise permissible, any necessary modifications to a test procedure will be proposed before issuance of an ANOPR in the standards development process, and a final test procedure modifying test procedures as necessary will be issued prior to a NOPR on proposed standards. See section 7(a) and (b). This document is part of the rulemaking for the test procedure for distribution transformers. DOE has not initiated a rulemaking regarding amended standards for distribution transformers, and to the extent DOE does propose amended standards for distribution transformers, such a proposal will be addressed in a separate rulemaking.

NEMA commented that it believes there is no need for significant revisions to test procedures for distribution transformers. (NEMA, No. 14 at p. 2). NRECA and APPA commented that further action to issue new standards or new test procedures to support new standards is not necessary for this product category. (NRECA, No. 22 at p. 1; APPA, No. 24 at p. 2) Per EPCA (as discussed in section I.A of this document), DOE must evaluate test procedures for each type of covered equipment at least once every 7 years. 42 U.S.C. 6314(a)(1). Consistent with NEMA's comments, based on DOE's evaluation, the proposals in this NOPR are minor revisions that do not make significant changes to the test procedure. Therefore, the proposed amendments would have no impact to measured values.

CA IOUs urged DOE to work with Institute of Electrical and Electronics Engineers (IEEE) and the Distribution Transformers subcommittee to gather the necessary data and information requested in the RFI. (CA IOUs, No. 18 at p. 1) In response to the September 2017 TP RFI, DOE received relevant information and data from multiple stakeholders to inform the test procedure rulemaking. The proposals presented in this document reflect DOE's consideration of all the information received in response to the RFI. Through this NOPR, DOE is providing further opportunity for the public to provide comments, information, and data on proposed amendments to the test procedure for distribution transformers.

B. Scope

The applicability of the test procedure is provided in 10 CFR 431.193, which states that ''the test procedures for measuring the energy efficiency of distribution transformers for purposes of EPCA are specified in appendix A to this subpart.'' DOE has established energy conservation standards for low-voltage dry-type (LVDT) distribution transformers, liquid-immersed distribution transformers, and medium-voltage dry type (MVDT) distribution transformers at 10 CFR 431.196. In this NOPR, DOE proposes to state explicitly that the scope of the test procedure is limited to the scope of the distribution transformers that are subject to energy conservation standards. DOE proposes to modify text in 10 CFR 431.193 accordingly.

C. Definitions

This notice proposes clarifying amendments to the test procedure for distribution transformers. A ''transformer'' is a device consisting of 2 or more coils of insulated wire that transfers alternating current by electromagnetic induction from 1 coil to another to change the original voltage or

current value. 10 CFR 431.192. A ''distribution transformer'' is a transformer that: (1) Has an input voltage of 34.5 kV or less; (2) has an output voltage of 600 V or less; (3) is rated for operation at a frequency of 60 Hz; and (4) has a capacity of 10 kVA to 2500 kVA for liquid-immersed units and 15 kVA to 2500 kVA for dry-type units. *Id.* The term ''distribution transformer'' does not include a transformer that is an autotransformer; drive (isolation) transformer; grounding transformer; machine-tool (control) transformer; nonventilated transformer; rectifier transformer; regulating transformer; sealed transformer; special-impedance transformer; testing transformer; transformer with tap range of 20 percent or more; uninterruptible power supply transformer; or welding transformer. *Id.*

A ''liquid-immersed distribution transformer'' is a distribution transformer in which the core and coil assembly is immersed in an insulating liquid. *Id.* A ''low-voltage dry-type distribution transformer'' is a distribution transformer that has an input voltage of 600 volts or less; is air-cooled; and does not use oil as a coolant. *Id.* A ''medium-voltage dry-type distribution transformer'' means a distribution transformer in which the core and coil assembly is immersed in a gaseous or dry-compound insulating medium, and which has a rated primary voltage between 601 V and 34.5 kV. *Id.*

In this NOPR, DOE proposes additional specification to the test procedure scope and instructions. As part of that objective, DOE is proposing new definitions for two terms: ''terminal'' and ''auxiliary device.'' Details are provided in sections III.C.2.b and III.C.2.c of this document. In addition, DOE is proposing minor editorial updates to the following definitions: ''low-voltage dry-type distribution transformer'' and ''reference temperature.'' Details are provided in section III.C.3 of this NOPR.

1. Rectifier Transformers

Rectifier transformers are defined in the CFR to operate at the fundamental frequency of an alternating-current system and are designed to have one or more output windings connected to a rectifier. 10 CFR 431.192. Rectifier transformers are among the exclusions to the term ''distribution transformer'' at 10 CFR 431.192. Because rectifier transformers are not classified as distribution transformers, they are not subject to the energy conservation standards at 10 CFR 431.196.

Drive transformers are defined in the CFR to isolate electric motors from the line, accommodate the added loads of drive-created harmonics, and are designed to withstand the mechanical stresses resulting from both alternating- and direct-current motors drives. 10 CFR 431.192. Drive transformers are among the exclusions to the term ''distribution transformer'' at 10 CFR 431.192. Although drive and rectifier transformers are defined differently, they would share many features. First, both are isolation (*i.e.,* not auto-) transformers. Second, both are typically exposed to (and must tolerate) significant drive-/power supply-created harmonic current. Finally, both are likely to include design features enabling them to bear mechanical stress resulting from rapid current changes that may arise from operation of motors and other industrial equipment.

Suresh commented that many distribution transformers supply loads that may have greater harmonic current due to the ubiquity of electronics, which typically include rectifiers and which tend to produce harmonic current. Suresh stated that, as a result, it could be argued that most distribution-type transformers meet the present definition of the terms ''rectifier transformer'' or ''drive transformer.'' Suresh suggested that those terms be removed from the list of exclusions to the term ''distribution transformer.'' (Suresh, No. 8 at p. 1) Suresh also suggested that the definition of ''rectifier transformer'' be limited to transformers that supply loads that are composed of at least 75 percent power electronics. (Suresh, No. 9 at p. 1)

The definition of ''rectifier transformer'' should not be interpreted as broadly as the commenter suggests it could be; *i.e.,* this term is not intended to describe a large number of transformers intended for general power distribution service. Linking a definition of ''rectifier transformer'' to supply of loads composed of greater than 75 percent power electronics would not be sufficient to designate a distribution transformer, as it may not be possible for a manufacturer to know in advance what fraction of the distribution transformer's load will include power electronics.

DOE reviewed industry standards [5] and internet-published manufacturer literature [6] to identify physical attributes that could be used to distinguish transformers requiring design modification to serve large rectifiers and drives from transformers designed for general-purpose use. In that review, DOE did not observe feature combinations that could be used to reliably identify rectifier transformers. For example, DOE did not find a quantification of how much harmonic current a transformer would need to accommodate to become suitable for service as a rectifier transformer. Although DOE was not able to find a candidate replacement definition for ''rectifier transformer'' (or ''drive transformer'') in review of certain industry standards and internet-published literature, DOE is interested in receiving feedback on how such a definition may be identified.

DOE requests comment on: (1) Whether the current definition of rectifier transformer is sufficiently specific, (2) if not, what modifications would make it sufficiently specific, and (3) whether partial output phase shift, harmonic current tolerance, or other electrical properties may be used to reliably identify rectifier transformers.

DOE requests comment on: (1) Whether the current definition of drive transformer is sufficiently specific, (2) if not, what modifications would make it sufficiently specific, and (3) the level of technical similarity drive transformers bear to rectifier transformers.

2. New Definitions

In this NOPR, DOE proposes to include new definitions for ''per-unit load,'' ''terminal,'' and ''auxiliary devices.'' Section 5.1 of Appendix A references ''per-unit load'' in reference to calculation of load-losses. Appendix A references ''terminal'' in several provisions regarding test set-up, including in sections 3.3.1.2(c), 3.3.2, and 4.4.2(a)(3). Section 4.4.1 of appendix A provides that measurement corrections are permitted but not required for losses from auxiliary devices. Neither ''per-unit load,'' ''terminal,'' nor ''auxiliary device'' is currently defined in the regulatory text. DOE's justification for proposing to add these terms is discussed further in the following sections.

a. Per-Unit Load

A distribution transformer is regularly operated in-service at load levels less than the full rated load, based on distribution system design, and fluctuations in customer energy

[5] DOE reviewed the following industry standards:

(1) IEEE C57.18.10–1998, ''IEEE Standard Practices and Requirements for Semiconductor Power Rectifier Transformers''.

(2) IEC 61378–1:2011, ''Converter transformers—Part 1: Transformers for Industrial Applications''.

(3) IEEE 100–2000, ''The Authoritative Dictionary of IEEE Standards Terms; Seventh Edition''.

(4) IEC 60050,[5] ''International Electrotechnical Vocabulary''.

[6] internet-published literature included product guides, brochures, manuals, and drawings.

demand. Throughout the test procedures and energy conservation standards for distribution transformers, various terms are used to refer to a less-than-full rated load, including ''percent load,'' ''percent of nameplate-rated load,'' ''percent of the rated load,'' or ''per unit load level.'' 10 CFR 431.192, 10 CFR 431.196, and appendix A. DOE is proposing to define a single term, ''per-unit load,'' to mean the fraction of rated load, and to consolidate the usage of these various terms to the new term ''per-unit load'' in all instances identified. Consolidating the terms would provide consistency throughout the DOE test procedure and would affirm that the different terms have the same meaning.

DOE requests comment on its proposed definition of ''per-unit load'' and its proposal to consolidate the usage of various terms referring to less-than-full rated load to the single term ''per-unit load.''

b. Terminal

DOE is proposing to define ''terminal'' to mean ''a conducting element of a distribution transformer providing electrical connection to an external conductor that is not part of the transformer.'' This definition is based on the definition for ''terminal'' in IEEE C57.12.80–2010, ''IEEE Standard Terminology for Power and Distribution Transformers.'' To clarify how losses should be measured, DOE is proposing to specify that load and no-load loss measurements are required to be taken only at the transformer terminals, as discussed further in Section III.J.3 of this document.

DOE requests comment on its proposed definition of ''terminal.''

c. Auxiliary Device

Section 4.5.3.1.2 of appendix A specifies ''during testing, measured losses attributable to auxiliary devices (*e.g.,* circuit breakers, fuses, switches) installed in the transformer, if any, that are not part of the winding and core assembly, may be excluded from load losses measured during testing.'' DOE has received inquiries from manufacturers regarding whether certain other internal components of distribution transformers are required by DOE test procedures to be included in the loss calculation, or whether they are considered an auxiliary device. Beyond the listed examples of circuit breakers, fuses, and switches, the current test procedures do not specify which other components may be considered auxiliary devices. DOE is not aware of a prevailing industry definition for the term ''auxiliary device,'' as applied to distribution transformers. The language at section 4.5.3.1.2 of appendix A provides example-based guidance regarding which components of a distribution transformer are regarded as auxiliary devices. In this NOPR, however, DOE is proposing to establish a definition of the term ''auxiliary device'' based on a specific list of all components and/or component functions that would be considered auxiliary devices and, therefore, be optionally excluded from measurement of load loss during testing.

The auxiliary device examples listed at section 4.5.3.1.2 of appendix A (circuit breakers, fuses, and switches) all provide protective function, but do not directly aid the transformer's core function of supplying electrical power. Additionally, the term ''device'' may imply a localized nature, rather than a diffuse system or property of the transformer.

DOE researched commonly included components in distribution transformers and identified circuit breakers, fuses, switches, and surge/lightning arresters as devices which provide protective function and upon which the transformer does not rely to provide its primary function of supplying electrical power at a certain voltage. Accordingly, DOE is proposing to define ''auxiliary device'' to mean ''a localized component of a distribution transformer that is a circuit breaker, switch, fuse, or surge/lightning arrester.''

DOE requests comment on its proposed definition of ''auxiliary device,'' and whether certain components should be added or removed from the listed auxiliary devices and why. DOE also requests comment on whether it is appropriate to include functional component designations as part of a definition of ''auxiliary device'' and, if so, which functions and why.

3. Updated Definitions

a. Low-Voltage Dry-Type Distribution Transformer

As described, the definition of ''low-voltage dry-type distribution transformer'' specifies that it does not use oil as a coolant, among other criteria. DOE is proposing to update the definition for ''low-voltage dry-type distribution transformer'' by replacing the term ''oil'' with ''insulating liquid'' within the definition, in conjunction with DOE's proposal to consolidate multiple terms to ''insulating liquid,'' as described in section III.D.2 of this document. DOE is proposing this update to reflect that the term is inclusive of all insulating liquids, including those identified in IEEE C57.12.90–2015.

DOE requests comment on its proposed updated definition of ''low-voltage dry-type distribution transformer.''

b. Reference Temperature

As currently defined at 10 CFR 431.192, ''reference temperature'' means 20 °C for no-load loss, 55 °C for load loss of liquid-immersed distribution transformers at 50 percent load, and 75 °C for load loss of both low-voltage and medium-voltage dry-type distribution transformers, at 35 percent load and 50 percent load, respectively. It is the temperature at which the transformer losses must be determined, and to which such losses must be corrected if testing is done at a different point.

DOE is proposing to update the definition for ''reference temperature'' by removing references to the numerical temperature values required for certification with energy conservation standards. DOE proposes to retain the conceptual definition of reference temperature and to instead rely on appendix A to specify the numerical temperature values. As proposed, ''reference temperature'' would mean the temperature at which the transformer losses are determined, and to which such losses must be corrected if testing is done at a different point. This proposal would allow use of the term reference temperature outside the context of conditions required for certification with energy conservation standards (*i.e.,* voluntary representations at additional temperature values, as described in section III.E.4 of this document).

DOE requests comment on its proposed updated definition of ''reference temperature.''

D. Updates to Industry Testing Standards

The current DOE test procedure for distribution transformers is based on the following industry testing standards (*See* 71 FR 24972, 24982 (April 27, 2006)):

- NEMA TP 2–1998, ''Standard Test Method for Measuring the Energy Consumption of Distribution Transformers'' (NEMA TP 2–1998)
- IEEE C57.12.90–1999, ''IEEE Standard Test Code for Liquid-Immersed Distribution, Power and Regulating Transformers and IEEE Guide for Short Circuit Testing of Distribution and Power Transformers''
- IEEE C57.12.91–2001, ''IEEE Standard Test Code for Dry-Type Distribution and Power Transformers''

- IEEE C57.12.00–2000, ''IEEE Standard General Requirements for Liquid-Immersed Distribution, Power and Regulating Transformers''
- IEEE C57.12.01–1998, ''IEEE Standard General Requirements for Dry-Type Distribution and Power Transformers Including those with Solid Cast and/or Resin Encapsulated Windings''

In addition, the DOE test procedure also incorporates relevant parts of NEMA TP 2–2005, which also references the aforementioned IEEE industry standards. DOE determined that basing the procedure on multiple industry standards, as opposed to adopting an industry test procedure (or procedures) without modification, was necessary to provide the detail and accuracy required for the Federal test procedure, with the additional benefit of providing manufacturers the Federal test procedure in a single reference. 71 FR 24972, 24982 (April 27, 2006).

In the September 2017 TP RFI, DOE requested comments on the benefits and burdens of adopting industry standards without modification. 82 FR 44347, 44351 (September 22, 2017). Without identifying specific benefits, NEMA stated generally that there is benefit to adopting an industry standard, but if doing so, DOE should limit the reference to the measurement of losses and retain DOE's existing calculation for efficiency. (NEMA, No. 14 at p. 9) As stated, DOE has already based the current test procedure on industry standards developed by NEMA and IEEE. Additionally, if DOE were to adopt an industry standard without modification, the resulting changes to the test procedure could require manufacturers to retest and recertify, because such an incorporation by reference (IBR) would require updating a majority of the current test procedure. At this time, DOE is not proposing to incorporate industry standards into its test procedures for distribution transformers.

1. Updates to NEMA TP 2

Since the April 2006 TP final rule, NEMA has rescinded NEMA TP 2–2005.[7] DOE received one comment regarding the withdrawal; Suresh commented that because NEMA TP 2 was rescinded, it should not be used as a reference for determining efficiency for distribution transformers. Suresh also stated that the current IEEE/ANSI C57.12.00, C57.12.90 and C57.12.91 are adequate for testing. (Suresh, No. 9 at p. 1)

EPCA requires that DOE base the test procedure on NEMA TP 2–1998. (42 U.S.C. 6293(b)(10)(A)) As discussed in the previous section, the DOE test procedure is based on NEMA TP 2–1998, NEMA TP 2–2005, as well as four widely used IEEE standards, *i.e.,* IEEE.C57.12.00, IEEE C57.12.01, IEEE C57.12.90 and IEEE C57.12.91. *See* 71 FR 24972, 24982 (April 27, 2006). In addition, these IEEE standards, are all referenced standards in NEMA TP 2–2005. Therefore, even though the DOE test procedure is based on NEMA TP 2–1998 and NEMA TP 2–2005, because the DOE test procedure also follows the appropriate IEEE standards, DOE finds that the current stand-alone test procedure is still appropriate.

2. Updates to IEEE Standards

As discussed previously in this section, the DOE test procedure mirrors four widely used IEEE industry standards.[8] IEEE develops and maintains a large number of standards for a broad range of electrical, electronic, and communications equipment and protocols. Since the April 2006 TP final rule, all of the four IEEE standards have been updated. The latest versions of the IEEE standards include IEEE C57.12.90–2015, IEEE C57.12.91–2011, IEEE C57.12.00–2015, and IEEE C57.12.01–2015. Table III.2 provides a list of old and new versions of each of these IEEE standards.

TABLE III.2—IEEE INDUSTRY STANDARDS VERSIONS AND SUMMARY

IEEE standard	Old version (year)	New version (year)	Content
C57.12.00	2000	2015	General electrical and mechanical requirements for liquid-immersed distribution transformers.
C57.12.01	1998	2015	General electrical and mechanical requirements for dry-type distribution transformers.
C57.12.90	1999	2015	Methods for performing tests specified in C57.12.00 and others for liquid-immersed distribution transformers.
C57.12.91	2001	2011	Methods for performing tests specified in C57.12.01 and others for dry-type distribution transformers.

DOE reviewed the updated IEEE standards to determine whether any of the updates should be incorporated into the DOE test procedure. The four IEEE standards are not relevant to the DOE test procedure in their entirety, as they include specifications and test methods beyond those required to measure efficiency, such as test methods for polarity, phase-relation, dielectric, and audible sound-level. These industry standards do not contain minimum energy efficiency (or maximum energy consumption) requirements. DOE performed the review as follows: (1) DOE identified the sections of the IEEE industry standards that form the basis of the DOE test procedure, (2) DOE compared those sections between the old and new versions of the IEEE industry standards, and (3) DOE determined which of the changes were editorial versus which could be improvements to the DOE test procedure.

The IEEE C57.12.00 and IEEE C57.12.01 standards include general electrical and mechanical requirements and specify test methods for liquid-immersed and dry-type distribution transformers, by referring to the test methods in IEEE C57.12.90 and IEEE C57.12.91, respectively. Sections 5, 8, and 9 of IEEE C57.12.90–2015 and IEEE C57.12.91–2011 provide the resistance measurements, the no-load loss test, and the load loss test, respectively, which provide the basis for the DOE test procedure. In general, DOE did not find major changes in sections 5, 8, and 9 between IEEE C57.12.90–2015 and IEEE C57.12.91–2011, and IEEE C57.12.90–1999 and IEEE C57.12.91–2001, respectively. DOE did identify certain updates that would provide

[7] Standard Test Method for measuring the energy consumption of distribution transformers, available at: *https://www.nema.org/Standards/Pages/Standard-Test-Method-for-Measuring-the-Energy-Consumption-of-Distribution-Transformers.aspx.*

[8] The distribution transformers industry refers to these documents as ''standards'' because they reflect standardized, consensus-based methods of designing, constructing, naming, rating, and measuring performance of distribution transformers. This use of the term ''standards'' contrasts with that of DOE's Appliance Standards Program use of the term ''standards'' to refer to a minimum energy efficiency (or maximum energy consumption) requirement. These IEEE standards do not contain minimal energy thresholds or requirements.

supplemental detail to the current DOE test procedure and that reflect current industry practice in conducting the test procedure. Therefore, the adoption of these updates would further improve the DOE test procedure consistent with industry practice. Table III.3 summarizes the proposed updates.

TABLE III.3—PROPOSED UPDATES BASED ON IEEE STANDARDS

Topic	Proposed update based on IEEE standards
Consolidating the Terms ''Oil,'' ''Transformer Liquid,'' and ''Insulating Liquid''.	Replace the term ''oil'' and ''transformer liquid'' with ''insulating liquid'' in 10 CFR 431.192 and appendix A to reflect that the term is inclusive of all insulating liquids, including those identified in IEEE C57.12.90–2015.
Stability Requirement for Resistance Measurement	Specify, consistent with IEEE C57.12.90–2015, that resistance measurements are considered stable if the top insulating liquid temperature does not vary more than 2 °C in a one-hour period. (Appendix A, section 3.2.1.2(b)).
Automatic Recording of Data	Require automatic recording of data, as required in IEEE C57.12.90–2015 and IEEE C57.12.91–2011, using a digital data acquisition system. (Appendix A, section 4.4.2(b)).
Temperature Test System Accuracy	Relax the temperature test system accuracy requirements to be within ±1.5 °C for liquid-immersed distribution transformers, and ±2.0 °C for MVDT and LVDT distribution transformers, as specified in IEEE C57.12.00–2015 and IEEE C57.12.01–2015, respectively. (Appendix A, section 2.0).
Limits for Voltmeter-Ammeter Method	Permit use of the voltmeter-ammeter method when the rated current of the winding is less than or equal to 1A. Neither IEEE C57.12.90–2015 nor IEEE C57.12.90–2011 restrict usage of this method to certain current ranges. (Appendix A, section 3.3.2(a)).
Number of Readings Required for Resistance Measurement	Include the requirement that a minimum of four readings for current and voltage must be used for each resistance measurement, as specified in IEEE C57.12.90–2015. (Appendix A, section 3.3.2(b)).
Connection Locations for Resistance Measurements	Add resistance measurement specifications for single-phase windings, wye windings and delta windings, as provided in section 5.4.1 and 5.4.2 of IEEE C57.12.90–2015, and sections 5.6.1 through 5.6.3 of IEEE C57.12.91–2011. (Appendix A, section 3.4.1(g)–(i)).
Test Frequency	Require that all testing under the DOE test procedure is to occur only at 60 Hz. (Appendix A, sections 3.1(c), 4.1).
Polarity of Core Magnetization	Require that the polarity of the core magnetization be kept constant during all resistance readings. (Appendix A, section 3.4.1(f)).

The proposed updates listed in Table III.2 align with an industry-consensus standard, and therefore, would not increase testing burden because the industry-consensus standard reflects current testing practice. IEEE standards are voluntarily developed by industry with input from a range of stakeholders and are based on industry experience. The industry standards represent the industry's own position on what is the best approach to distribution transformer testing. Additionally, industry uses IEEE test procedures. For example, DOE found that municipal distribution transformer procurement contracts almost always require the transformer be tested in accordance with IEEE standards. Furthermore, several manufacturer catalogs also indicate that distribution transformers are tested in accordance with the pertinent IEEE standards.

The proposals listed in Table III.2 provide additional detail and direction to the current test procedures. The proposed updates requiring new or additional test requirements would not contradict the current DOE test requirements, were they to be made final. As discussed, these proposed clarifications reflecting the industry standards are already industry practice. As such, the proposals, if made final, would not change current measured values. Furthermore, providing additional specificity would improve the repeatability of the test procedure.

DOE requests comment on the proposed updates based on the latest version of the applicable IEEE standards for testing distribution transformers, and specifically regarding whether industry is already testing to the requirements of those IEEE standards.

DOE requests comment on the tentative determination that each of the proposals do not increase test cost or burden, and that they would not result in different measured values than the current test procedure.

E. Per-Unit Load Testing Requirements

Per-unit load (PUL) is the actual power supplied by a distribution transformer, divided by the distribution transformer's rated capacity. As discussed, it is also referred to as ''percent load,'' ''percent of nameplate-rated load,'' ''percent of the rated load,'' or ''per unit load level'' in 10 CFR 431.192, 10 CFR 431.196, and appendix A. In this NOPR, all instances are referred to as per-unit load, or PUL.

The efficiency of a distribution transformer varies depending on the PUL at which it is operating. However, the measurements obtained by testing a distribution transformer at one PUL can be used to mathematically determine the efficiency of the transformer at other PULs. For certifying compliance with the energy conservation standards, the efficiency is determined at a PUL of 50 percent for liquid-immersed transformers and MVDT distribution transformers, and a PUL of 35 percent for LVDT distribution transformers. 10 CFR 431.196 and appendix A. The PUL at which the efficiency of a distribution transformer is evaluated for compliance with the applicable energy conservation standard is generally referred to as the ''test PUL.'' The test procedure, however, does not require testing of the distribution transformer while operating at the test PUL. Section 5.1 of appendix A provides equations to calculate the efficiency of a distribution transformer at any PUL based on the testing of the distribution transformer at a single PUL.

Current industry practice is to test at 100 percent PUL and mathematically determine the efficiency at the applicable test PUL.

The test PUL is intended to represent the typical PUL experienced by in-service distribution transformers. However, some complications exist, including: (1) A given customer may not operate the transformer at a single constant PUL, and (2) a transformer model may be used at different PULs by different customers. In the September 2017 TP RFI, DOE requested comments and sought information on whether the test PUL accurately represents in-service distribution transformer performance, and provides test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle of an in-service transformer. 82 FR 44347, 44350 (September 22, 2017).

In addition, so that the test procedure could better reflect how distribution transformers operate in service, DOE stated in the September 2017 TP RFI that it may consider: (1) Revising the single test PUL to a multiple-PUL weighted-average efficiency metric, (2) revising the single test PUL to an alternative single test PUL metric that better represents in-service PUL, or (3) maintaining current single test PUL specifications. DOE received several comments on this topic, in addition to potential other metrics for energy conservation standards. 82 FR 44347, 44350 (September 22, 2017).

DOE received a number of comments stating that in-service PUL is diverse. (HVOLT, No. 3 at p. 16, Powersmiths, No. 11 at p. 1, NRECA, No. 22 at p. 2, NEMA, No. 14 at p. 2, EEI, No. 16 at p. 2, Howard Industries, No. 24 at p. 1) HVOLT stated that transformers are generally purchased in bulk and largely placed in stock to be applied as needed, and therefore, the same transformer may be placed in a light loaded or heavy loaded application. (HVOLT, No. 3 at p. 21) AK Steel commented that transformers of the same design operate at many different PULs, and when transformers are operated at higher PULs, the load loss will far exceed the no-load losses. (AK Steel, No. 6 at p. 1) NRECA commented that transformers have different efficiencies at different PULs, and PULs can change over the lifetime of a transformer. (NRECA, No. 22 at p. 2)

Several stakeholders also submitted information showing how observed in-service PULs are different than what was presented by DOE in the September 2017 TP RFI. 82 FR 44347, 44350 (September 22, 2017). Suresh supported re-assessing the current test PUL requirements to achieve the benefits of improved efficiency at optimum cost. (Suresh, No. 9 at p. 1) HVOLT commented that PUL data from loading studies show light average loads in rural settings and loads greater than 70 percent in some urban settings and for some commercial and industrial customers. (HVOLT, No. 3 at p. 16) Summary system load information provided by HVOLT, and referenced by EEI, of some of California's Pacific Gas and Electric (PG&E) regional commercial, industrial, and residential customers show diversity of annual and peak load factors as a function of what DOE assumes is system capacity. HVOLT also stated that American Electric Power (AEP) and PECO customer loads are also similarly diverse. (HVOLT, No. 3 at p. 16; EEI, No. 16 at p. 2) Metglas stated that PULs of 20 percent to 30 percent are typical of residential distribution transformers, as reported by APPA and NRECA in a February 2015 letter to the U.S. Environmental Protection Agency (EPA). (Metglas, No. 17 at p. 4) Howard Industries stated that it provides liquid-immersed units to rural electrical cooperatives with very light loading and heavy industrial customers with extremely high loading. (Howard Industries, No. 24 at p. 1)

Regarding the representativeness of the California data, EEI reasoned that it is likely that the annual load factors of transformers serving residential customers in California will be lower than the load factors of transformers serving homes in other parts of the United States due to the state's utility electric efficiency programs and building energy codes. EEI also indicated that the PG&E data is from 2006, and therefore does not account for the significant rise in the number of plug-in electric vehicles, which could further increase load factors. (EEI, No. 16 at pp. 2–3)

NEMA commented that it believes that the previous DOE distribution transformer rulemaking's investigations in typical field loading practices remain relevant and as accurate as is possible given the high variations in field conditions.[9] [10] [11] Additionally, NEMA mentioned certain IEEE studies that indicate that particular utilities practice very high loading levels, but that EPA's ENERGY STAR consideration for liquid-immersed distribution transformers showed several utilities lightly load their transformers, which happens mostly in rural electric markets. (NEMA, No. 14 at p. 2) APPA and NRECA stated that a ''one-size-fits-all'' energy conservation standard based on a single test PUL has restricted availability of the most cost-effective and energy efficient options. Further, APPA and NRECA stated that it is not possible to develop an energy conservation standard and test procedure that take into account the varied loading on a transformer (both from location to location, and on an hourly and seasonal basis). APPA and NRECA requested that DOE refrain from any future action with test procedures or energy conservation standards, stating that there would only be a burden (no benefit) associated with those changes. (APPA, No. 24 at p. 2; NRECA, No. 22 at p. 3)

DOE appreciates the data and information it received on the topic of in-service PULs. The data and comments received are consistent with DOE's understanding that the in-service PULs sustained by transformers are very diverse. This diversity of PUL is because the application of distribution transformers is itself diverse, ranging from light-loading to heavy-loading applications. DOE recognizes that the wide range of in-service conditions that transformers sustain means that the efficiency at the test PUL may not reflect the efficiency of any given transformer at its in-service PUL. The information supplied by stakeholders was either largely anecdotal, or limited utility customer meter data from which transformer loads may be inferred as a proxy. Both anecdotal and utility customer meter data are useful as they frame generally expected loading limits. Additionally, the customer load data contains detailed loading characteristics for small, specific populations. However, DOE notes that both are of limited representativeness. Given these factors, DOE finds the information available at this time for describing in-service PUL to be inconclusive, leaving DOE unable to demonstrate that an alternate test PUL is more representative than the existing test PUL.

[9] The result of DOE's distribution transformer load analysis for medium-voltage liquid-immersed distribution transformers are contained in the Life-cycle Cost and Payback Period spreadsheet tools for design lines (DL) 1 through 5 on the Forecast Cells tab. (available at: *https://www.regulations.gov/document?D=EERE-2010-BT-STD-0048-0767*)

[10] The result of DOE's transformer load analysis for LVDT distribution transformers are contained in the Life-cycle Cost and Payback Period spreadsheet tools for DLs 6 through 8 on the Forecast Cells tab. (available at: *https://www.regulations.gov/document?D=EERE-2011-BT-STD-0051-0085*)

[11] The result of DOE's transformer load analysis for MVDT distribution transformers are contained in the Life-cycle Cost and Payback Period spreadsheet tools for DL 9 through 13B on the Forecast Cells tab. (available at: *https://www.regulations.gov/document?D=EERE-2010-BT-STD-0048-0764*)

1. Multiple-PUL Weighted-Average Efficiency Metric

In the September 2017 TP RFI, DOE stated it would consider a multiple-PUL efficiency metric because the use of a weighted-average efficiency metric comprised of efficiency at more than one test PUL may better reflect how distribution transformers operate in service, as described in this document. As such, DOE requested data and information to inform a multiple-PUL metric. 82 FR 44347, 44350 (September 22, 2017).

The majority of stakeholders commented that including a multiple-PUL weighted-average efficiency metric would be overly burdensome on manufacturers. (HVOLT, No. 3 at p. 24; AK Steel, No. 6 at p. 2; Powersmiths, No. 11 at p. 2; Prolec-GE, No. 23 at p. 1–2; Howard Industries, No. 24 at p. 1) Specifically, Powersmiths commented that it would increase test burden, be difficult to agree on appropriate test PULs to include, present a consumer education challenge, and disadvantage small business manufacturers. (Powersmiths, No. 11 at p. 2) Prolec-GE stated that a multiple-PUL weighted-average efficiency metric would result in suboptimal, higher-cost designs. (Prolec-GE, No. 23 at p. 3) Howard Industries stated that no additional constraints or alternate metrics should be included because it will be too burdensome and costly. (Howard Industries, No. 24 at p. 2)

NEMA stated that physical testing at multiple PULs would result in significant technical challenges to keep winding temperatures managed under test conditions, adding significant complexity to the test procedures and introducing new sources for variation. NEMA stated that these conditions would be unavoidable and their impacts on testing would serve to further increase differences between test results and actual in-service conditions. Because of these challenges, NEMA asserted that testing at one load point is the most feasible method. (NEMA, No. 14 at p. 5) NEMA commented that currently, transformers are physically tested at 100 percent PUL and follow-on test points are calculated, and that this practice should be maintained. NEMA stated that the existing method is well-proven and well-understood by NEMA members and other stakeholders in the transformer industry as the best system to evaluate transformer performance. (NEMA, No. 14 at p. 5) NEMA also stated that using weighted-average loading in the application of energy conservation standards without consideration of how it affects measured efficiency values could be misleading. Adding a weighted-average formula requirement could also deny a customer who is certain of their field loading level from buying the most efficient transformer for their application. NEMA further commented that the current test PUL requirements allow for sufficient flexibility in field purchasing decisions today. (NEMA, No. 14 at p. 5)

ACEEE & ASAP commented that DOE should consider the benefits of ratings based on a weighted average of multiple load points, where weightings are based on expected hours of operation within bands around each load point. ACEEE & ASAP provided as an example, ratings based on the average load point (about 40 percent), and the 25th and 75th percentile load points (about 30 percent and 50 percent respectively), which they stated may improve representativeness and foster improved efficiency in the field. ACEEE & ASAP commented that in no case should DOE base ratings on extreme load conditions rarely seen in the field. They also commented that they understand AEDMs to be technically capable of supplying ratings at any load point and, therefore, that manufacturers should be able to certify to weighted-average ratings at very low additional costs. (ACEEE & ASAP, No. 15 at p. 3)

DOE appreciates the comments received regarding the multiple-PUL weighted-average efficiency metric. Based on comments received, DOE has tentatively determined that the range of in-service PULs is large, and varies depending on the application and location of distribution transformers. DOE recognizes that depending on the procedure for measuring and calculating the efficiency based on multiple test PULs, a change of metric may increase the current test burden, due to the need to re-test and re-certify performance to DOE.[12] In addition, consumers would need to be educated on how to interpret the new metric, which would not correspond to performance at any one test PUL, but would be based on multiple operating conditions. Lastly, available data describing this PUL variation is largely anecdotal and insufficient to show that a multiple-PUL weighted-average efficiency metric is more representative of in-service PUL than the existing metric. Specifically, a lack of information is available to determine which PULs would be appropriate as part of a multiple-PUL weighted efficiency metric, and how those PULs should be weighted. Given the drawbacks cited and the lack of evidence at this time to show a weighted-average metric is more representative than the existing metric, DOE is not proposing a multiple-PUL weighted-average efficiency metric.

2. Single-PUL Efficiency Metric

In the September 2017 TP RFI, DOE stated that for a single-PUL efficiency metric, it may consider either continuing to use the current single test PUL requirements, or revising the single test PUL to an alternate single test PUL, if it were to better reflect how distribution transformers operate in service. As such, DOE requested data and information to inform any changes to the metric. 82 FR 44347, 44350 (September 22, 2017).

A number of stakeholders commented in support of both a single-PUL efficiency metric and the existing test PUL requirements specified. (HVOLT, No. 3 at p. 21; Powersmiths, No. 11 at p. 3; NEMA, No. 14 at p. 2; NRECA, No. 22 at p. 3; Prolec-GE, No. 23 at p. 1; Howard Industries, No. 24 at p. 1) Specifically, Prolec-GE commented that it has not seen evidence warranting a change from the current 50 percent PUL requirement for liquid-immersed transformers. Prolec-GE stated that it is aware that some utilities assumed lower loads, as demonstrated by their Total Owning Cost (ToC)[13] [14] formulas and information presented during the development of the EPA ENERGY STAR program for liquid-filled distribution transformers; however, some are higher, though this is the exception. Prolec-GE stated that utilities do not know in advance where a transformer will be installed, and that they also plan for load growth. Therefore, Prolec-GE concluded that 50 percent PUL is reasonable. (Prolec-GE, No. 23 at p. 1) Howard Industries stated that no additional constraints or alternate metrics should be included because it would be too burdensome and costly. (Howard Industries, No. 24 at p. 2)

ACEEE & ASAP recommended 25 percent PUL for LVDT distribution

[12] Per-unit testing costs could be identical for a multiple-PUL metric versus the existing metric, if performance at each PUL is calculated from a single measurement point (rather than physical measurements at each PUL).

[13] The Total Owning Cost is the cost savings over the lifetime of the product, based on the utility's no-load and load loss evaluation factors. ToC takes into account not only the initial transformer cost, but also the cost to operate and maintain the transformer over its lifetime. The ToC formula is provided in the ENERGY STAR specification for distribution transformers that is currently under development: (*https://www.energystar.gov/products/spec/distribution_transformers_pd*).

[14] U.S. Department of Agriculture and Rural Development, Rural Utility Service (RUS), *Guide for Economic Evaluation of Distribution Transformers,* 2016, Bulletin 1724D–107, *https://www.rd.usda.gov/publications/regulations guidelines/bulletins/electric.*

transformers, 35 percent PUL for MVDT distribution transformers and 40 percent PUL for liquid-immersed distribution transformers, in addition to considering ratings based on a weighted-average PUL. ACEEE & ASAP stated that these values would be more representative, based on data provided in the RFI. (ACEEE & ASAP, No. 15 at p. 3) EEI recommended 75 percent PUL for liquid-immersed distribution transformers, if two single-PUL ratings are not proposed (as discussed in section III.E.1 of this NOPR). (EEI, No. 16 at p. 4) Powersmiths commented that the current DOE test procedure at 35 percent PUL for LVDT distribution transformers does not reflect real world efficiency, and that field measurements showed most of the market either at less than 15 percent PUL or greater than 50 percent PUL. However, given the real-world variability in loading and harmonic content, Powersmiths stated that it would not be practical or economically viable to establish a revised test protocol that would capture all these scenarios, as it would be onerous for the whole industry to follow. (Powersmiths, No. 11 at p. 2)

With respect to test PUL requirements, DOE considered updating the test PUL requirements to an alternative single test PUL if it were to better reflect how distribution transformers operate in service. As discussed in sections III.E and III.E.1, however, DOE has tentatively determined that the range of in-service PULs is large, and that the available information describing in-service PUL is inconclusive, which leaves DOE unable at this time to show that an alternate single test PUL is more representative of in-service PUL than the existing single test PUL. DOE recognizes that a change of metric may increase the current test burden (depending on the procedure for measuring and calculating efficiency at the new test PUL), due to the need to re-test and re-certify performance to DOE. Therefore, given the limitations of the currently available data and lack of a strong indication that an alternate single test PUL would be more representative than the existing single test PUL, DOE is not proposing to amend the test PUL requirements. As such, DOE has tentatively determined to maintain the current single test PUL requirements in appendix A, which require that efficiency must be determined at a single test PUL of 50 percent for both liquid-immersed and MVDT distribution transformers, and that efficiency must be determined at a single test PUL of 35 percent for LVDT distribution transformers.

However, DOE agrees there is value in providing a basis for voluntary representations of additional performance information to foster better-informed decision-making by consumers. Additional performance information at other PULs would allow consumers to maximize transformer efficiency based on their needs. As such, in this NOPR, DOE is proposing a test procedure for voluntary representations at additional PULs and/or reference temperatures, which is discussed further in section III.E.4 of this document.

3. Other Efficiency Metric Recommendations

In addition to the potential use of alternate efficiency metrics on which DOE requested comment in the September 2017 TP RFI, DOE also received other recommendations from stakeholders to take under consideration. AK Steel recommended that DOE implement an efficiency requirement at 100 percent PUL, in addition to the current test requirement. (AK Steel, No. 6 at p. 2) EEI commented that based on factors that could both increase and decrease transformer load, it supported having two PUL tests for liquid-filled transformers: One at the current 50 percent PUL and a second at 75 percent PUL. (EEI, No. 16 at p. 4) Howard Industries stated that no additional constraints or alternate metrics should be included because it will be too burdensome and costly. (Howard Industries, No. 24 at p. 2)

Metglas recommended DOE use the approach considered by EPA's ENERGY STAR program, where EPA proposed to expand the number of PULs that would be optimized to four PULs (25, 35, 50, and 65 percent), in addition to the ToC process.[15] Metglas stated that better matching the purchased unit's actual operating PUL with optimized PULs for those units could result in significant energy savings. (Metglas, No. 17 at p. 2) Metglas commented that the addition of a 100 percent PUL only reduces the competitiveness of all transformers made with low core-loss material since, to meet the (infrequently observed) 100 percent PUL, all low core-loss material transformers become more expensive rather than being the best economic solution for many actual operating PULs. (Metglas, No. 17 at p. 5) NRECA advocated for the ToC process, similar to the EPA program, which allows individual utilities to select optimal designs for their systems and expected PUL. (NRECA, No. 22 at p. 3)

HVOLT stated that the advent of new low core-loss materials has created the opportunity for transformers with low no-load loss to carry greater load losses and remain compliant; the low core-loss distribution transformers may perform comparatively better than conventional-core distribution transformers at low PULs and comparatively worse at high PULs. (HVOLT, No. 3 at p. 22–23) HVOLT recommended that to limit the potential for large load losses in transformers built with low core-loss materials, a constraint on total losses at full load is warranted to ensure that highly loaded transformers remain efficient. *Id.* HVOLT suggested that total losses do not require any new measurements, but would simply be calculated. In addition, HVOLT recommended a limit which it characterized as an additional energy conservation standard, on full load total losses as ''limit = $1 + 1/(0.9 \times 0.5^2) \times$ watts'' at 50 percent PUL for medium-voltage distribution transformers and ''limit = $1 + 1/(0.82 \times 0.35^2) \times$ watts'' at 35 percent PUL for low-voltage distribution transformers. HVOLT stated a generous tolerance could also be applied to that limit. (HVOLT, No. 3 at p. 22)

NEMA, on the other hand, stated that proposals encouraging the restriction of losses at high PULs are based on very simplistic assumptions that do not consider the real-life restrictions a design must meet. NEMA stated that assuming a design can be optimized to have the peak efficiency at the required PUL, and that the load losses can be indefinitely increased through greater use of low core-loss materials like amorphous metal, does not adequately consider other restrictions transformers have in real life; for example, the capacity of the cooling system. (NEMA, No. 14 at p. 5)

To summarize, the recommendations for additional metrics as provided by commenters are: (1) Efficiency requirements at 100 percent PUL in addition to current DOE requirements, (2) efficiency requirements at 75 percent PUL in addition to current DOE requirements at 50 percent PUL for liquid-immersed transformers, (3) optimization at 25, 35, 50 and 65 percent PUL, in addition to the ToC process, similar to EPA's ENERGY

[15] The EPA's ENERGY STAR specification for distribution transformers (version 1.0) is currently under development. The final draft specification was published on December 9, 2016 (*https://www.energystar.gov/products/spec/distribution_transformers_pd*). On September 27, 2017, EPA published guidance on buying energy efficient medium-voltage liquid-immersed transformers, which includes recommended energy efficiency criteria at 25 percent, 35 percent, 50 percent and 65 percent PULs, in addition to using the ToC equation: *https://www.energystar.gov/products/avoiding_distribution_transformer_energy_waste.*

STAR guidance, and (4) constraint on total losses, in addition to current DOE requirements. The above recommendations address issues beyond the test procedure, *i.e.,* they would result in multiple standards applicable to a single distribution transformer.

DOE also received comments from Powersmiths stating that customers incorrectly understand transformers to operate at the minimum efficiencies required by DOE even at operating conditions that are different than in the DOE test procedure. (Powersmiths, No. 11 at p. 2) Powersmiths commented that the current DOE test procedure should remain, but also require a disclaimer label or associated literature that the efficiency applies only under ideal linear load (*i.e.,* at the DOE test PUL), and that actual efficiency may be lower. (Powersmiths, No. 11 at p. 3) Powersmiths stated that, if manufacturers offer transformers optimized for other PULs, then they should be required to back up their performance claims by clearly defining whatever test protocols are used, supported by audit and by certification to a recognized testing body. (Powersmiths, No. 11 at p. 3)

As discussed in sections III.E.1 and III.E.2 of this document, any changes or additional metrics may increase the current test burden, due to the need to re-test and re-certify performance to DOE. Additionally, consumers would need to be educated on how to interpret any of the new metrics recommended in the comments above. Lastly, DOE lacks sufficient information on in-service PUL to support whether an alternate test PUL or metric would be more representative of field conditions, so as to justify requiring testing at that alternate test PUL. Therefore, DOE finds that proposing a new metric is not justified at this time.

However, to provide manufacturers the opportunity to inform end users of the performance of a distribution transformer at conditions other than those required to demonstrate compliance with the DOE efficiency standard, DOE is proposing to provide explicitly for voluntary representation at additional PULs and reference temperatures. Additional representations would allow customers to better predict how different distribution transformers would operate under the individualized conditions of that customer. Further discussion on this proposal is provided in section III.E.4.

4. Voluntary Representations of Efficiency at Additional PULs

DOE received one comment suggesting that public reporting of additional data would increase consumer information informing purchasing decisions. In response to the September 2017 TP RFI, MKC commented that rather than specify one test point, which is typically at rated voltage and 50 percent load, the test procedure should determine both no-load loss and load loss. MKC stated that the two values can determine the efficiency of the transformer under any loading condition, and that the no-load loss and load loss would be determined by Clause 8 and 9 from IEEE C57.12.90, or a similar test method. (MKC, No. 4 at p. 1)

Manufacturers are prohibited under 42 U.S.C. 6314(d) from making representations respecting the energy consumption of covered equipment or cost of energy consumed by such equipment, unless that equipment has been tested in accordance with the applicable DOE test procedure and such representations fairly disclose the results of that testing. As discussed, the current DOE test procedure requires that for both liquid-immersed and MVDT distribution transformers, efficiency is determined at a single test PUL of 50 percent, and that for LVDT distribution transformers, efficiency is determined at a single test PUL of 35 percent. Section 3.5 of appendix A. In addition, efficiency must be determined at the reference temperature of 20 °C for no-load loss for all distribution transformers; 55 °C for load loss for liquid-immersed distribution transformers at the required test PUL of 50 percent; 75 °C for load loss for MVDT distribution transformers at the required test PUL of 50 percent; and 75 °C for load loss for LVDT distribution transformers at the required test PUL of 35 percent. 10 CFR 431.192. The DOE test procedure specifies reference temperature requirements only at the test PULs currently required to comply with the energy conservation standards.

In this NOPR, DOE is proposing amendments to the test procedure to permit manufacturers to make voluntary representations of additional performance information of distribution transformers when operated under conditions other than those required for compliance with the energy conservation standards for distribution transformers at 10 CFR 431.196. The proposal would help consumers make better purchasing decisions based on their specific installation conditions. Therefore, DOE proposes in a new section 7 of appendix A to allow manufacturers to represent efficiency, no-load loss, or load loss at additional PULs and/or reference temperatures, as long as the equipment is also represented in accordance with DOE's test procedure at the mandatory PUL and reference temperature. When making voluntary representations, best practice would be for the manufacturers also to provide the PUL and reference temperature corresponding to those voluntary representations.

Table III.4 provides a summary of the proposal for voluntary representations at any PUL.

TABLE III.4—SUMMARY OF VOLUNTARY REPRESENTATION PROPOSAL

	Mandatory certified values *			Voluntary representations (proposed)		
	Metric	PUL (percent)	Reference temperature for load loss (°C)	Metric	PUL (percent)	Reference temperature (°C)
Liquid Immersed	Efficiency	50	55	Efficiency, load loss, no load loss.	Any	Any.
MVDT		50	75			
LVDT		35	75			

* Efficiency must be determined at a reference temperature of 20 °C for no-load loss for all distribution transformers.

DOE requests comment on the proposal to amend the DOE test procedure to permit manufacturers to make voluntary representations at any additional PUL and/or reference temperature, and whether this would assist consumers in making better purchasing decisions based on their specific installation conditions. DOE requests comment on whether the current DOE test procedure would be appropriate at non-mandatory PULs and reference temperatures.

F. Purchasing Decision

While a customer can specify that transformer efficiency be optimized to their in-service PUL, the transformer must also comply with the energy conservation standard at the test PUL. The lowest-cost transformer design would likely have an efficiency peak at or near the test PUL, and that the low-cost transformers would experience reduced efficiency when operated at PULs other than the test PUL. Therefore, considering there may be variation between the test PUL specified in the test procedure and actual in-service use, DOE requested comment on the extent to which efficiency is considered for transformer purchasing decisions.

DOE received several comments from stakeholders indicating that first cost is the primary driver for purchasing decisions. HVOLT commented that efficiency is only considered for simple verification that the transformer is DOE-compliant. Beyond that, HVOLT asserted, purchase decisions are mostly made on price, delivery and other user specifications. (HVOLT, No. 3 at p. 17) AK Steel stated that it has consistently seen that when purchasing transformers, first cost, including transformer cost plus installation, is the primary driver in purchasing decisions. (AK Steel, No. 6 at p. 2)

In addition, DOE received several comments stating that most manufacturers and customers ensure only that transformers are DOE compliant when considering efficiency. Specifically, AK Steel, which produces electrical steel used in distribution transformers, stated that performance exceeding the DOE energy conservation standard is not a consideration when AK Steel prices its electrical steel. (AK Steel, No. 6 at p. 2) AK Steel commented that transformer efficiency at current test PULs have little influence on transformer efficiency at higher PULs, which AK Steel states is especially apparent when lower-cost, less-efficient windings are used. AK Steel asserts that as a result, users will purchase DOE-compliant transformers that have significantly lower efficiency than more appropriately designed units for in-service PULs. (AK Steel, No. 6 at p. 1)

Metglas, which also produces electrical steel used in distribution transformers, suggests that by allowing those purchasing distribution transformers the opportunity to better match projected operating conditions with transformers better optimized for those conditions that significant energy saving could be realized. (Metglas, No. 17 at p. 2) Powersmiths recognized DOE's identification of the business opportunity for transformer manufacturers to produce application-specific optimization that can realize low transformer lifecycle cost to customers, but stated that this opportunity has been ignored by manufacturers. (Powersmiths, No. 11 at p. 2) NEMA stated that some utility customers who know their anticipated loading do seek information from their transformer supplier about whether a transformer can be designed to meet best efficiency at that PUL. (NEMA, No. 14 at p. 3)

However, Powersmiths stated that despite smaller manufacturers having more flexibility to provide application-specific models that deliver increased efficiency in each targeted application, these manufacturers do not typically offer additional choices beyond what is required by the DOE test procedure. Additionally, having a multitude of models optimized for different applications is not compatible with the low cost, high volume manufacturing and distribution model, which drives the fewest product configurations. (Powersmiths, No. 11 at pgs. 2–3) Powersmiths further commented that manufacturers design their transformers with peak efficiency at the single DOE test PUL to the detriment of all other operating conditions, such that they are the lowest cost supplier in the competitive market. (Powersmiths, No. 11 at p. 2) Prolec-GE similarly stated that it does not see benefit in representing efficiency at a level higher than the DOE minimum, because most customers only want assurance that the transformer is compliant. (Prolec-GE, No. 23 at p. 5) NEMA further stated that while a transformer can be designed to be optimized for PULs other than DOE's test PUL, it must also meet the current DOE efficiency standard, and the two are not necessarily the same, and in many cases, the two efficiency points cannot be reconciled in a feasible design and manageable cost. (NEMA, No. 14 at p. 3)

DOE also received several other comments regarding other ways customers evaluate their purchasing decisions. NEMA stated that members in liquid-filled product categories seek specifications from customers which include ToC as a way of addressing efficiency in the purchasing decision process. However, NEMA stated that ToC does not guarantee that the resulting design will exceed the current DOE efficiency levels by any appreciable margin. NEMA commented that the NEMA dry-type manufacturers rarely experience ToC requests. NEMA stated that there is a niche market for high efficiency LVDT distribution transformers, but the size of the market is unknown to NEMA members. For MVDT distribution transformers, NEMA stated that efficiency does not appear to be a significant consideration; price and delivery remain top considerations. (NEMA, No. 14 at p. 3) Prolec-GE stated that 30 to 40 percent of its customers (mostly in rural utility service and rural electric cooperative markets) evaluate, and half end up buying the best ToC choice. (Prolec-GE, No. 23 at p. 2) Prolec-GE further stated meeting the DOE standard at 50 percent PUL and customer ToC formula can be challenging without pushing first cost too high. (Prolec-GE, No. 23 at p. 2) Howard Industries commented that approximately 50 percent of its utility customers are still using the ToC approach when purchasing liquid-immersed transformers. (Howard Industries, No. 24 at p. 1)

DOE acknowledges that many transformers are designed such that their efficiency peaks at the DOE test PULs, which will allow for the lowest costs. DOE also acknowledges that some transformers are optimized at PULs other than those required by DOE's test procedure. DOE also notes that customers use several different methods to determine the appropriate distribution transformers for their application, including the ToC method. DOE's requirements do not restrict the use of any of the purchasing decision methods, as long as both the test procedure and standards requirements are met.

As described previously in section III.E.4 of this NOPR, in an effort to provide manufacturers greater opportunity to describe equipment performance at additional PULs, DOE is proposing amendments to the DOE test procedure that would allow manufacturers to make voluntary representations at additional PULs and reference temperatures, using the DOE test procedure. Manufacturers would still be required to comply with the current energy conservation standards requirements but would be allowed to voluntarily represent their equipment at

a variety of PUL conditions. This information could be used by consumers to make better informed purchasing decisions based on their specific installation conditions.

G. Load Growth

In the September 2017 TP RFI, DOE discussed estimates for the load growth of distribution transformers used in the April 2013 ECS final rule. 82 FR 33437, 44349. These estimates contribute to the description of typical loading experienced by a distribution transformer in-service. DOE estimated a one percent annual increase over the life of the transformer to account for connected load growth for liquid-immersed transformers, and no load growth over the life of LVDT and MVDT distribution transformers. DOE requested comments regarding the load growth estimate over the life of distribution transformers currently being installed, and how that could inform test requirements in the DOE test procedure. *Id.*

DOE received several comments on this topic. HVOLT stated that it does not have any hard data on the load growth estimate over the life of the distribution transformer. HVOLT commented that utilities are generally focused on peak power demand, as non-peak loading does little to affect distribution system design needs, and that load growth normally results from new customers or loads being added to existing circuits. In addition, HVOLT stated that the expanded electrification of motor vehicles and new commercial and industrial processes are likely to increase the load on MVDT distribution transformers. On the other hand, HVOLT commented that the loads on LVDT distribution transformers may be relatively constant. (HVOLT, No. 13 at p. 17)

ACEEE & ASAP commented that a 0.5 percent growth rate is consistent with the EIA's Annual Energy Outlook 2017 projected load growth of 0.56 percent per year in its reference case. (ACEEE & ASAP, No. 15 at p. 2) EEI commented that it believes the overall trends in load could be increasing over time given some of the significant changes occurring in the electricity industry. Specifically, the trends include the deployment of Smart Grid technologies, the increased variability of distributed and renewable energy sources at different times of day in renewable distributed generation systems, increased deployment of electric transportation options, and the increased electrification of industrial and other operations; and asks that any change in the test procedure account for these changes. (EEI, No. 16 at p. 3) NRECA stated that it is not possible to tell if load factors over the lifetime of transformers will decrease due to energy efficiency or greatly increase due to penetration of electric vehicles and other distributed energy resources. (NRECA, No. 22 at p. 2)

DOE appreciates the comments and opinions submitted on the topic of load growth sustained by in-service transformers. As commenters noted, a number of trends and factors may impact the load growth realized by distribution transformers and that some of these trends would have opposing impacts (*e.g.,* improvements in efficiencies versus the increased penetration of electric vehicles). At the present, DOE does not have sufficient data to propose changing the current test procedure to account for transformer load growth. However, DOE will continue to examine trends in transformer load growth and may address the issue as necessary and feasible in any future rulemaking.

H. Temperature Correction

DOE's current test procedure specifies temperature correction of measured loss values, a process that calculates the losses of a transformer as though its internal temperature during testing were equal to a ''reference'' temperature. The reference temperature provides a common point of comparison, so that the effect of temperature on efficiency is diminished. If transformers in service do not reach the same internal temperature (under identical operating conditions, including ambient temperature and PUL), temperature correction may weaken the ability of the test procedure to predict relative in-service performance. In the September 2017 TP RFI, DOE requested comments, data and information on whether the current temperature correction is appropriate or whether alternative approaches should be considered. 82 FR 44347, 44350 (September 22, 2017) DOE received several comments on the September 2017 TP RFI regarding this topic. All supported maintaining the current requirements.

Several comments directly supported the current method of temperature correction. Howard Industries stated that the current method for temperature correction is appropriate and applicable. (Howard, No. 24 at p. 1) NEMA commented that the temperature conditions may vary greatly during operation, and that use of a common reference temperature allows the DOE test procedure to fairly compare different products. (NEMA, No. 14 at p. 4) Accordingly, NEMA suggested that the current test procedure requirements for temperature correction are adequate. NEMA also stated that internal temperature of a transformer is driven by both electrical losses and cooling ability. Cooling ability changes as a function of ambient temperature, which may vary widely even for a single design. In addition, cooling ability is closely coupled with design features that also affect many other electrical and mechanical characteristics of the unit. NEMA stated that as a result, developing a characteristic relationship between operating temperature and PUL is quite difficult. NEMA stated that maintaining the 75 °C reference temperature provides consistency and is the best approach given the uncertainty [in true operating temperature]. (NEMA, No. 14 at p. 4) NEMA further commented that any change in requirements would cause performance data across current and future designs to become noncomparable. (NEMA, No. 14 at p. 4) NEMA also commented that modifications to the existing internal temperature correction methodology and test PUL requirement, which would require adjustment to temperature correction requirements, would cause manufacturers significant burden. (NEMA, No. 14 at p. 4)

Other comments concurred with the general concept of temperature correction. HVOLT stated that temperature generally rises with load current to the 1.6 power under steady state conditions. (HVOLT, No. 3 at p. 19) HVOLT further stated that temperature correction is not of significant concern, because even when it is performed, the true temperature of tested transformers is accurately measured and recorded. (HVOLT, No. 3 at p. 19) Howard Industries commented that temperature will rise with increasing PUL; winding rises are generally designed to meet 65 °C rise at full load. (Howard Industries, No. 24 at p. 1)

After further consideration, including the comments received, DOE is not proposing changes to the current temperature correction requirements. In response to NEMA's comment that transformer operating temperature is a function of heat buildup, ambient conditions, and transformer cooling design, DOE observes that, while it is true that no single reference temperature could represent all operating conditions, it may be possible to develop a methodology that accounts for heat buildup and transformer cooling design. DOE may explore the possibility in a future notice.

I. Multiple Voltage Capability

Some distribution transformers have primary windings (''primaries'') and secondary windings (''secondaries'') that may each be reconfigured, for example either in series or in parallel, to accommodate multiple voltages. Some configurations may be more efficient than others. Such transformers are often purchased with the intent of upgrading the local power grid to a higher operating voltage and thereby reducing overall system losses.

Section 4.5.1(b) of appendix A requires that for a transformer that has a configuration of windings that allows for more than one nominal rated voltage, the load losses must be determined either in the winding configuration in which the highest losses occur, or in each winding configuration in which the transformer can operate. Similarly, section 5.0 of appendix A states that for a transformer that has a configuration of windings that allows for more than one nominal rated voltage, its efficiency must be determined either at the voltage at which the highest losses occur, or at each voltage at which the transformer is rated to operate. Under either testing and rating option (*i.e.,* testing only the highest loss configuration, or testing all configurations), the winding configuration that produces the highest losses must be tested and consequently must comply with the applicable energy conservation standard.

Whereas IEEE directs distribution transformers to be shipped with the windings in series,[16] a manufacturer physically testing for DOE compliance may need to disassemble the unit, reconfigure the windings to test the configuration that produces the highest losses, test the unit, then reassemble the unit in its original configuration, which adds time and expense.

NEMA stated that the majority of distribution transformers are used in service in the highest-voltage configuration and that some transformers will have slightly higher losses in the lowest-voltage configuration. NEMA stated that, based on its calculations, the difference in load loss between the as-shipped version as compared to the highest loss configuration is no more than two percent. NEMA further asserts that the difference in testing as-shipped versus highest-loss configuration has minimal impact in determining the numerical value of efficiency, and that the difference is smaller than the error introduced by the DOE formula for scaling load loss to the specified test PUL. (NEMA, No. 14 at p. 6) Prolec-GE commented that switching to as-shipped voltage configuration would improve reliability and reproducibility because it would facilitate more physical testing of transformers, and would improve representativeness because it would better align with performance experienced by users. (Prolec-GE, No. 23 at p. 4) Prolec-GE also stated that it uses an AEDM and supports its continued allowance because reconfiguring transformers from the as-shipped winding configuration would be quite costly. (Prolec-GE, No. 23 at p. 4) Both Prolec-GE and NEMA suggested that DOE should harmonize with industry standards and practices by permitting testing in the as-shipped winding configuration. (Prolec-GE, No. 23 at p. 6, NEMA, No. 14 at p. 6)

DOE recognizes that, for manufacturers physically testing their transformers, reporting losses in the same configuration in which the transformers are shipped, which IEEE instructs to be the in-series configuration, may be less burdensome than requiring testing in the configuration that produces the highest losses.[17] DOE notes, however, that neither Prolec-GE nor NEMA provided transformer design data to support their claim that the difference in losses would be minimal when comparing between transformers rated ''as-shipped'' versus the current requirement that transformers be rated in their highest loss configuration. Conversely, the losses of different winding positions can vary considerably and, as a result, no single winding configuration will always yield the greatest loss (or lowest efficiency) for all distribution transformers. Manufacturers may decide to test in multiple or all configurations to find the highest loss configuration. DOE remains concerned that there is no reliable way to predict in which winding configuration a transformer will be operated over the majority of its lifetime.

Furthermore, as an alternative to physical testing, DOE provides for certification using an AEDM, which is a mathematical model based on the transformer design. 10 CFR 429.47. The shipped configuration has no bearing on the AEDM calculation, and an AEDM can determine the highest-loss configuration instantly. The current requirement to test and certify based on the highest-loss configuration of the windings confers a consumer benefit by ensuring the consumer receives at least the tested level of performance. 71 FR 24972, 24985 (April 27, 2006). DOE notes that most transformers are currently certified using the AEDM.

Further, changing the requirement of testing in the configuration from producing the highest losses to ''as-shipped'', may increase the calculated efficiency, changing the basis upon which existing energy conservation standards were established. The losses between different winding configurations can be significant, and to avoid potential backsliding DOE would need to amend its energy conservation standard to account for testing in a different configuration.[18] This could also necessitate the need for manufacturers of transformers with multiple windings to re-test and re-certify their performance to DOE.

Based on these considerations, DOE is not proposing to amend the requirement relating to winding configuration.

DOE requests comment on secondary winding configurations. DOE also requests comment on the magnitude of the additional losses associated with the less efficient configurations as well as the relative period of operation in each winding configuration.

J. Other Test Procedure Topics

In addition to the proposed updates to the DOE test procedure provided in the preceding sections, DOE also considered whether the existing test procedure would benefit from any further revisions and/or reorganizing. Additional issues are discussed in the following section.

1. Per-Unit Load Specification

DOE proposes to centralize the PUL specifications, both for the certification to energy conservation standards and for use with a voluntary representation. Currently, the PUL for certification to energy conservation standards is specified in multiple locations, including 10 CFR 431.192 (definition of reference temperature), 10 CFR 431.196, section 3.5(a) of appendix A, and section 5.1 of appendix A. DOE proposes to consolidate the PUL specification into one location—a newly proposed section 2.1 of appendix A. Additionally, DOE proposes to provide in the proposed section 2.1 of appendix A that the PUL specification can be any

[16] Institute of Electrical and Electronics Engineers, Inc (IEEE); *IEEE Standard General Requirements for Liquid-Immersed Distribution, Power, and Regulating Transformers,* 2017, IEEE Standard C57.12.00–2015, *https://standards.ieee.org/findstds/standard/C57.12.00-2015.html.*

[17] *Ibid.*

[18] EPCA contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered equipment. (42 U.S.C. 6295(o)(1); 42 U.S.C. 6316(a))

value for purposes of voluntary representations. The consolidation would enhance readability of the test procedure and more clearly communicate DOE's PUL requirements with respect to certification to energy conservation standards and voluntary representations. The updates do not change existing test PUL requirements with respect to certification to energy conservation standards. Instead, the updates improve clarity with respect to selection of PUL for voluntary representations versus certification to energy conservation standards.

DOE also proposes editorial changes to section 5.1 of appendix A to support the consolidated approach to PUL specification. Section 5.1 contains equations used to calculate load-losses at any PUL. Section 5.1 of appendix A uses language that limits its applicability to certification to energy conservation standards only. For example, it references the ''specified energy efficiency load level'' (*i.e.,* the PUL required for certification to energy conservation standards) specifically. DOE proposes to generalize the language in this section to reference the PUL selected in the proposed section 2.1.

2. Reference Temperature Specification

Similar to PUL, DOE proposes to consolidate the reference temperature specifications for certification to energy conservation standards and for the proposed voluntary representations. Currently, the reference temperature for certification to energy conservation standards is described in multiple locations, including 10 CFR 431.192 (definition of reference temperature), section 3.5(a) of appendix A, and section 4.4.3.3 of appendix A. DOE proposes to consolidate the reference temperature specification into one location—a newly proposed section 2.2 of appendix A. Additionally, DOE proposes to describe in the proposed section 2.2 of appendix A that the reference temperature specification can be any value for purposes of voluntary representations. Similar to PUL, this consolidation would enhance readability of the test procedure and more clearly communicate DOE's reference temperature requirements with respect to certification to energy conservation standards or voluntary representations. The updates do not change existing reference temperature requirements with respect to certification to energy conservation standards. Instead, the updates improve clarity with respect to selection of reference temperature for voluntary representations versus certification to energy conservation standards.

DOE also proposes editorial changes to section 3.5 and section 4.4.3.3 of appendix A to support the consolidated approach to reference temperature specification. Section 3.5 of appendix A provides reference temperatures for certification to energy conservation standards. However, considering DOE has consolidated reference temperature specifications into one location (proposed section 2.2), DOE has removed the same specification in section 3.5 so that the section could be applicable to determine voluntary representations.

Section 4.4.3.3 of appendix A provides the specifications and equations used for correcting no-load loss to the reference temperature. Specifically, the section provides an option for no correction if the no-load measurements were made between 10 °C and 30 °C. This tolerance is only applicable for certification to energy conservation standards (it is a ±10 °C range around the 20 °C reference temperature). For simplicity, DOE proposes no such tolerance for voluntary representations at additional reference temperatures, so that all measured values would be adjusted using the reference temperature correction formula. Finally, DOE proposes to remove any reference to a reference temperature of 20 °C so that the section would be applicable to determine voluntary representations.

3. Measurement Location

DOE proposes to specify that load and no-load loss measurements are required to be taken only at the transformer terminals. Accordingly, in this NOPR, DOE has proposed a definition for ''terminal,'' as described in section III.C.2.b. DOE notes that section 5.4 of IEEE.C57.12.90–2015 and section 5.6 of IEEE C57.12.91–2011 specify terminal-based load-loss measurements. In addition, section 8.2.4 of both IEEE.C57.12.90–2015 and IEEE C57.12.91–2011 provides the same for no-load loss measurement. These documents reflect current industry practices and manufacturers are already measuring losses at the transformer terminals. Therefore, in this NOPR, DOE proposes to specify in section 4.3(c) of appendix A that both load loss and no-load loss measurements must be made from terminal to terminal.

4. Specification for Stabilization of Current and Voltage

Section 3.3.2 and 3.3.1 of appendix A describe a voltmeter-ammeter method and resistance bridge methods, respectively, for measuring resistance. Both methods require measurements to be stable before determining the resistance of the transformer winding being measured. Specifically, the voltmeter-ammeter method in section 3.3.2(b) of appendix A requires that current and voltage readings be stable before taking simultaneous readings of current and voltage to determine winding resistance. For the resistance bridge methods, section 3.3.1 of appendix A requires the bridge be balanced (*i.e.,* no voltage across it or current through it) before determining winding resistance. Both methods allow for a resistor to reduce the time constant of the circuit, but do not explicitly specify how to determine when measurements are stable. DOE notes that IEEE C57.12.90–2015, IEEE C57.12.91–2011, IEEE C57.12.00–2015, and IEEE C57.12.01–2015 do not specify how to determine that stabilization is reached. Section 3.4.2 of appendix A provides related guidelines for improving measurement accuracy of resistance by reducing the transformer's time constant. However, section 3.4.2 also does not explicitly provide for the period of time (such as a certain multiple of the time constant) necessary to achieve stability. In this NOPR, DOE is seeking further information on how industry currently determines that measurements have stabilized before determining winding resistance using both voltmeter-ammeter method and resistance bridge methods.

DOE requests comments regarding when, or at what number of time constants, stability is reached for the voltmeter-ammeter method and the resistance bridge method.

5. Ambient Temperature Tolerances

In response to the September 2017 TP RFI, DOE received one comment concerning potential burden arising from the requirement to maintain the temperatures of both the testing laboratory and the transformer within certain ranges. Specifically, NEMA recommended that DOE increase the temperature tolerances when testing dry-type transformers, which require maintaining the laboratory ambient temperature within a range of 3 °C for 3 hours before testing, and maintaining transformer internal temperature (if ventilated) or surface temperature (if sealed) within 2 °C of the laboratory ambient temperature.

NEMA stated that these temperature limits may be burdensome in laboratories that are not climate controlled, and that an alternate method to the temperature limits may be a development of a mathematical correction factor. NEMA acknowledged, however, that in the experience of its

membership, the temperature requirements generally presented little challenge.

As stated, EPCA requires that DOE establish test procedures that are not unduly burdensome to conduct. Whereas widening tolerances of temperatures (or other measured parameters) may reduce testing cost, it may impact the reproducibility and repeatability of the test result. In the case of these particular temperature boundaries, that NEMA's membership is generally not experiencing difficulty in meeting them may suggest that they are appropriately sized. DOE does not have data regarding typical ranges of laboratory ambient temperature and, as a result, cannot be certain that reduction in temperature tolerance would not harm reproducibility, repeatability, and accuracy and cause future test results to become incomparable to past data. For these reasons, DOE is not proposing amendments to the laboratory ambient temperature and transformer internal temperature requirements.

DOE seeks comment on its proposal to maintain the laboratory ambient and transformer internal temperature requirements with no changes.

6. Field Test Equipment

MKC commented regarding potential difficulties inherent in using conventional test equipment with deployed, operational distribution transformers. MKC described and recommended alternative test equipment. (MKC, No. 4 at pp. 1–2) DOE observes that manufacturers and other parties testing distribution transformers are free to use any variety of equipment that meets the requirements set forth in appendix A.

7. Harmonic Current

Harmonic current refers to electrical power at alternating current frequencies greater than the fundamental frequency. In electrical power applications, harmonic current is typically regarded as undesirable; nonetheless, distribution transformers in service are commonly subject to (and must tolerate) harmonic current of a degree that varies by application. Test procedures for distribution transformers at sections 4.4.1(a) and 4.4.3.2(a) of appendix A direct use of a sinusoidal waveform when evaluating efficiency in distribution transformers.

Regarding test setup, Powersmiths commented that it would not be practical for the test procedure to address the harmonic content experienced in every customer's installation. (Powersmiths, No. 11 at p. 2) DOE recognizes that transformers in service are subject to a variety of harmonic conditions, and that the test procedure must provide a common basis for comparison. Currently, the test procedure states that transformers designed for harmonic currents must be tested with a sinusoidal waveform (*i.e.,* free of harmonic current), but does not do so for all other varieties of transformers. However, the intent of the test procedure is for all transformers to be tested with a sinusoidal waveform, as is implicit in section 4.4.1(a) of appendix A. To clarify this test setup requirement, DOE proposes to modify section 4.1 of appendix A to read ''. . . Test all distribution transformers using a sinusoidal waveform (k=1).'' This is consistent with industry practice and manufacturers are already testing all distribution transformers using a sinusoidal waveform.

DOE seeks comment on its proposal to modify section 4.1 of appendix A to read ''. . . Test all distribution transformers using a sinusoidal waveform (k=1).''

8. Other Editorial Revisions

DOE proposes the following editorial updates to improve the readability of the test procedure and provide additional detail: (i) Revising ''shall'' (and a single instance of ''should'' in the temperature condition requirements at section 3.2.2(b)(3)) to ''must'' in appendix A, (ii) clarifying the instructional language for recording the winding temperature for dry-type transformers (section 3.2.2 of appendix A), (iii) separating certain sentences into enumerated clauses (section 3.2.2(a) of appendix A),[19] (iv) identifying the corresponding resistance measurement method sections (section 3.3 of appendix A), (v) replacing a reference to ''uniform test method'' with ''this Appendix'' (section 3.3 of appendix A), (vi) removing reference to guidelines under section 3.4.1, *Required actions,* of appendix A to clarify that section establishes requirements, (vii) specifying the maximum amount of time for the temperature of the transformer windings to stabilize (section 3.2.2(b)(4) of appendix A [20]), (viii) removing references to the test procedure in 10 CFR 431.196, and (ix) replacing any reference to accuracy requirements in ''section 2.0'' and/or ''Table 2.0'' to ''section 2.3'' and/or ''Table 2.3,'' accordingly.

Section 3.2.2 of appendix A requires that, for testing of both ventilated and sealed units, the ambient temperature of the test area may be used to estimate the winding temperature (rather than direct measurement of the winding temperature), provided a number of conditions are met, including the condition that neither voltage nor current has been applied to the unit under test for 24 hours (provided in section 3.2.2(b)(4) of appendix A). The same section also allows for the initial 24 hours to be increased to up to a maximum of an additional 24 hours, so as to allow the temperature of the transformer windings to stabilize at the level of the ambient temperature. Based on the requirement, the total amount of time allowed would be a maximum of 48 hours. As such, in this NOPR, DOE proposes to specify explicitly that, for section 3.2.2(b)(4) of appendix A, the total maximum amount of time allowed is 48 hours.

DOE is also proposing conforming amendments to the energy conservation standard provisions. 10 CFR 431.196 establishes energy conservation standards for certain distribution transformers. Immediately following each table of standards, a note specifies the applicable test PUL and DOE test procedure. For example, in 10 CFR 431.196(a) the note reads, ''Note: All efficiency values are at 35 percent of nameplate-rated load, determined according to the DOE Test Method for Measuring the Energy Consumption of Distribution Transformers under Appendix A to Subpart K of 10 CFR part 431.'' Because 10 CFR 431.193 already requires that testing be in accordance with appendix A, DOE proposes to remove the references to the test procedure in 10 CFR 431.196. DOE proposes to maintain the portion of the note identifying the PUL corresponding to the efficiency values, for continuity and clarity.

As discussed in section III.J.1 and section III.J.2, DOE is proposing to clarify the PUL and reference temperature specifications for certification to energy conservation standards, and provide PUL and reference temperature specifications for voluntary representations, with a new section 2.1 for PUL requirements and section 2.2 for reference temperature requirements in appendix A. Accordingly, DOE proposes that the accuracy requirements previously provided in section 2.0 be moved to section 2.3 in appendix A. In addition, DOE proposes to re-number Table 2.1, Test System Accuracy Requirements For Each Measured Quantity, to Table 2.3. Lastly, DOE proposes to update cross-

[19] Under the changes proposed in this document, section 3.2.2(a) of appendix A would be split into section 3.2.2(a) and section 3.2.2(b).

[20] Under the changes proposed in this document, this section would become section 3.2.2(c)(4) of appendix A.

references in appendix A to the accuracy requirements in section 2.0 and/or table 2.1, to section 2.3 and/or table 2.3. The cross-references occur in section 3.1(b), section 3.3.3, section 3.4.2(a), section 4.3(a), section 6.0 and section 6.2 of appendix A.

K. Sampling, Representations, AEDMs

The certification and compliance requirements for distribution transformers are codified at 10 CFR part 429. DOE's sampling requirements are provided at 10 CFR 429.47. The sampling requirements, among other things, state that, (1) the provisions of 10 CFR 429.11, General sampling requirements for the selected units to be tested, apply, (2) a manufacturer must use a sample of at least five units if more than five units have been manufactured over a span of six months (10 CFR 429.47(a)(2)(i)(A)), and (3) efficiency of a basic model may be determined through testing, in accordance with appendix A, or through application of an AEDM under the requirements of 10 CFR 429.70. (10 CFR 429.47(a)(2)(i)(B))

DOE's requirements related to AEDMs are at 10 CFR 429.70. This section specifies under which circumstances an AEDM may be developed, validated, and applied to performance ratings for certain covered products and equipment.

In the September 2017 TP RFI, DOE requested feedback on the current sampling requirements; on whether manufacturers typically represent the minimum efficiency standard, the maximum efficiency allowable, or a different value; and regarding the usefulness of the AEDM provisions. 82 FR 44347, 44351 (September 22, 2017) DOE received several comments on the September 2017 TP RFI regarding these topics.

HVOLT commented that it believes the represented value calculations are useful in describing tolerance and objectives; large volumes of production have an easier means of achieving average performance than very small volumes of transformers. (HVOLT, No. 3 at p. 29) NEMA commented that the opportunity to use AEDM must be preserved, or burden will be raised for some manufacturers, and that DOE should maintain the status quo and afford manufacturers flexibility. (NEMA, No. 14 at p. 7) Howard Industries also commented that it uses the AEDM method to the fullest because it is too burdensome to physically test all units. (Howard Industries, No. 24 at p. 2) DOE appreciates stakeholders' comments and is not proposing changes to the AEDM provisions.

HVOLT stated that it believes all manufacturers test each transformer manufactured for losses, and that normally distribution transformers are overdesigned to minimize the possibility of non-compliant designs. (HVOLT, No. 3 at p. 28) Suresh stated that for units lower than 500 kVA, some manufacturers adopt bulk testing for a given rating at a time, and the average efficiency is determined, and that in some cases, manufacturers do not test all of their units because they test a statistically significant number of units to demonstrate the efficiency. (Suresh, No. 9 at p. 1) As discussed previously, DOE's sampling requirements require that for ratings developed using testing (rather than an AEDM) a manufacturer must use a sample of at least five units if more than five units have been manufactured over a span of six months (10 CFR 429.47(a)(2)(i)(B)), or as many as have been produced if five or fewer have been manufactured over a span of six months (10 CFR 429.47(a)(2)(i)(A)).

NEMA recommended that DOE consider providing software for manufacturers to help with reporting, and that this could be designed to contain all the raw data and the represented efficiency calculations. (NEMA, No. 14 at p. 8) DOE does provide product-specific templates for certifying basic models, which can be found on the following website: *https://www.regulations.doe.gov/ccms/templates.* However, DOE does not provide software for certification reporting. It is the manufacturer's responsibility to certify its products (or equipment) as required by DOE under 10 CFR part 429. Further, the manufacturer must decide how to represent the efficiency of a transformer between the limits of the energy conservation standard and the maximum representation allowed by 10 CFR 429.47(a)(2).

DOE received no other comments on the current sampling, representation and AEDM requirements. DOE is not proposing amendments to the sampling and AEDM requirements.

L. Test Procedure Costs, Harmonization, and Other Topics

1. Test Procedure Costs and Impact

EPCA requires that test procedures proposed by DOE not be unduly burdensome to conduct. In this NOPR, DOE proposes to amend the existing test procedure for distribution transformers by revising certain definitions, incorporating new definitions, incorporating revisions based on the latest versions of the IEEE industry standards, including provisions to allow manufacturers to use the DOE test procedure to make voluntary representations at additional PULs and/or reference temperatures, and reorganizing content among relevant sections of the CFR to improve readability. The proposed amendments would primarily provide updates and supplemental details for how to conduct the test procedure and do not add complexity to test conditions/setup or add test steps. In accordance with EPCA, DOE has tentatively determined that these proposed amendments would not be unduly burdensome for manufacturers to conduct. Further, DOE has tentatively determined that the proposal would not impact testing costs already experienced by manufacturers. DOE estimates based on a test quote from a laboratory that the cost for testing distribution transformers using the existing test procedure is approximately $400 per unit tested and that this figure would not change in response to the changes in this proposed rule. In summary, the proposals reflect and codify current industry practice.

The proposed amendments would not impact the scope of the test procedure. The proposed amendments would not require the testing of distribution transformers not already subject to the test procedure at 10 CFR 431.193 (*i.e.,* the proposal would not require manufacturers to test autotransformers, drive (isolation) transformers, grounding transformers, machine-tool (control) transformers, nonventilated transformers, rectifier transformers, regulating transformers, sealed transformer; special-impedance transformer; testing transformer; transformer with tap range of 20 percent or more; uninterruptible power supply transformer; or welding transformer, which are presently not subject to testing). The proposed amendments would not alter the measured energy efficiency or energy use of the distribution transformers. Manufacturers would be able to rely on data generated under the current test procedure should the proposed amendments be finalized. Further, the amendments proposed in this document, if finalized, would not require the purchase of additional equipment for testing.

DOE is proposing to adopt definitions for ''PUL,'' ''terminal'' and ''auxiliary device.'' The proposed definitions are intended to provide additional specificity in the application of the test procedure. The proposed definitions match current industry application of the test procedure and, if finalized, would not impact the conduct of the test or testing costs experienced by

manufacturers. DOE is also proposing to specify that both load loss and no-load loss measurements must be made from ''terminal to terminal.'' Measuring losses at the transformer terminals reflects current industry practices. In addition, the DOE test procedure already explicitly requires certain measurements at the terminals; specifically, the kelvin bridge method for determining resistance measurements in section 3.3.1.2(c), the voltmeter-ammeter method for determining resistance measurements in section 3.3.2(c), and the no-load loss test method in section 4.4.2(a)(3). Furthermore, taking other measurements (whose measurement locations are not explicit in the test procedure) at locations other than the terminal would yield results formed of mutually incongruous components, and would leave unclear what the test procedure was purporting to represent. Therefore, DOE initially concludes that the proposal to specify that both load loss and no-load loss measurements must be made from ''terminal to terminal'' reflects current practice and would not add any additional testing cost.

DOE is proposing a number of updates to its test procedures based on updates to the relevant IEEE standards. In addition to proposals that reflect non-substantive editorial updates to the IEEE standards (*i.e.,* consistent use of the term ''insulating liquid''), DOE is proposing to specify parameters for determining stability when making resistance measurements, explicitly require the automatic recording of data, specify the number of readings required for resistance measurement, specify the connection locations for resistance measurements, explicitly state the required test frequency, and require the polarity of the core magnetization be kept constant during all resistance readings. These proposed revisions, which are based on updates to the IEEE standards, reflect industry consensus and current practice. As such, these proposed revisions, if made final, would not impact test costs.

DOE is proposing an amendment to the test procedures to permit manufacturers to make voluntary representations of the performance (*i.e.,* efficiency, load loss, no load loss) of distribution transformers at conditions other than those required for compliance testing (*i.e.,* at additional PULs and manufacturer selected reference temperature). Under DOE's proposal in this document, manufacturers would be permitted to make representations using the DOE test procedure regarding the performance of distribution transformers under a wider range of operating conditions. The additional representations would be voluntary.

DOE estimates that if a manufacturer chose to make such voluntary representations, no additional testing cost would be incurred because the voluntary representations could be determined mathematically, without any additional testing. As discussed previously, manufacturers typically test distribution transformers at 100 percent PUL; performance at other PULs (including the PULs required for compliance with the energy conservation standards) is calculated mathematically. Appendix A provides equations [21] that manufacturers can use to (1) calculate no-load and load losses at any reference temperature and (2) calculate load losses at any PUL. These equations are currently used to calculate performance at the DOE-required conditions, but these same equations can also be used to calculate performance at additional conditions (of PULs and reference temperatures) for any voluntary representations, without the need to conduct additional testing.

A manufacturer could choose to re-test rather than mathematically determine the values for voluntary representations at other PULs or reference temperatures. However, the proposed provision regarding voluntary representations does not necessitate additional testing, were a manufacturer to choose to make voluntary representations. In addition, DOE is not requiring any certification or reporting of voluntary representations. For these reasons, no additional costs or test burden would be incurred for voluntary representations.

In addition, DOE is also proposing to centralize the PUL and reference temperature specifications in appendix A, both for the certification to energy conservation standards and for use with a voluntary representation. The updates are not substantive and do not change existing test PUL requirements with respect to certification to energy conservation standards. Rather, the consolidation would enhance readability of the test procedure and more clearly communicate DOE's PUL requirements with respect to certification to energy conservation standards and voluntary representations.

The other proposed amendments are mainly clerical or editorial in nature, and if finalized, they would not impact the measured test results or impact the test costs.

DOE requests comment on its understanding of the impact and associated costs of the proposed test procedure. To the extent commenters believe that manufacturers would not be able to rely on data generated under the current test procedure should the proposed amendments be finalized, DOE requests comment on the potential associated costs.

2. Harmonization With Industry Standards

As discussed in section III.D, the test procedure for distribution transformers at appendix A mirrors language contained in several industry standards: NEMA TP 2–1998; IEEE C57.12.90–1999; IEEE C57.12.91–2001; IEEE C57.12.00–2000; and IEEE C57.12.01–1998. DOE notes that when establishing the test procedure for distribution transformers, DOE determined that basing the procedure on multiple industry standards, as opposed to adopting an industry test procedure (or procedures) without modification, was necessary to provide the detail and accuracy required for the DOE test procedure, with the additional benefit of providing manufacturers the DOE test procedure in a single reference. As such, DOE relied heavily on the techniques and methods from NEMA TP 2–1998, NEMA TP 2–2005 and the four IEEE standards in developing the DOE test procedure. Both versions of NEMA TP 2 reference the IEEE standards as part of that industry test procedure. Specifically, the IEEE standards provide the test system accuracy requirements, resistance measurement test methods, and load loss and no-load loss test methods for both NEMA TP 2–1998 and NEMA TP 2–2005. Although both versions of NEMA TP 2 were designed to be a standard that extracts and presents pertinent parts of the IEEE standards, DOE determined the standard is not sufficiently clear and detailed to adopt as the DOE test procedure. Therefore, the current DOE test procedure is a stand-alone test procedure based on the multiple industry standards.

DOE seeks comment on the degree to which the DOE test procedure should consider and be harmonized further with the most recent relevant industry standards for distribution transformers, and whether any changes to the Federal test method would provide additional benefits to the public. DOE also requests comment on the benefits and burdens of adopting any industry/voluntary consensus-based or other appropriate test procedure, without modification.

[21] Equations are provided in section 5.1, section 4.4.3.3, and section 4.5.3.3 of appendix A.

3. Other Test Procedure Topics

In addition to the issues identified earlier in this document, DOE welcomes comment on any other aspect of the existing test procedure for distribution transformers not already addressed by the specific areas identified in this document. DOE particularly seeks information that would improve the representativeness of the test procedure, as well as information that would help DOE create a procedure that would limit manufacturer test burden. Comments regarding repeatability and reproducibility are also welcome.

DOE also requests information that would help DOE create procedures that would limit manufacturer test burden through streamlining or simplifying testing requirements. In particular, DOE notes that under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' Executive Branch agencies such as DOE must manage the costs associated with the imposition of expenditures required to comply with Federal regulations. See 82 FR 9339 (Feb. 3, 2017). Consistent with that Executive Order, DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations applicable to distribution transformers consistent with the requirements of EPCA.

M. Compliance Date and Waivers

EPCA prescribes that all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with an amended test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6314(d)(1)) If DOE were to publish an amended test procedure, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6314(d)(2)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. *Id.*

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget (OMB) has determined that test procedure rulemakings do not constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the OMB.

B. Review Under Executive Orders 13771 and 13777

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

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

(i) Eliminate jobs, or inhibit job creation;

(ii) Are outdated, unnecessary, or ineffective;

(iii) Impose costs that exceed benefits;

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

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

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

DOE initially concludes that this rulemaking is consistent with the directives set forth in these executive orders. The proposed rule would not yield any costs or cost savings.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) 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 DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website: *http://energy.gov/gc/office-general-counsel.*

DOE reviewed the test procedures considered in this proposed rule to amend the test procedure for distribution transformers under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003.

The Small Business Administration (''SBA'') considers a business entity to be a small business, if, together with its affiliates, it employs less than a threshold number of workers specified in 13 CFR part 121. The size standards and codes are established by the 2017 North American Industry Classification System (''NAICS'').

Distribution transformers manufacturers are classified under NAICS code 335311, power, distribution, and specialty transformer manufacturing. The SBA sets a threshold of 750 employees or fewer for an entity to be considered as a small business.[22] DOE conducted a focused inquiry into small business manufacturers of equipment covered by this rulemaking. DOE used its publicly available Compliance Certification Database [23] to create a list of companies that import or otherwise manufacture distribution transformers covered by this rulemaking. Using these sources, DOE identified a total of 21 distinct manufacturers of distribution transformers.

DOE then reviewed these data to determine whether the entities met the

[22] *https://www.sba.gov/document/support--table-size-standards.*

[23] *https://www.regulations.doe.gov/certification-data.*

SBA's definition of ''small business'' as it relates to NAICS code 335311 and to screen out companies that do not offer equipment covered by this rulemaking, do not meet the definition of a ''small business,'' or are foreign owned and operated. Based on this review, DOE has identified 10 manufacturers that are potential small businesses. Through this analysis, DOE has determined the expected effects of the proposed rule on these covered small businesses and whether an IRFA was needed (*i.e.,* whether DOE could certify that this rulemaking would not have a significant impact).

The proposed requirements of this NOPR neither expand the scope of equipment currently subject to test procedures, nor do they place additional requirements on distribution transformers currently subject to test procedures. In addition, the proposed amendments would not alter the measured energy efficiency/energy use of the distribution transformers. Manufacturers would be able to rely on data generated under the current test procedure should the proposed amendments be finalized. Therefore, no proposed revisions would increase burden on manufacturers.

However, in the NOPR, DOE is proposing to allow manufacturers to make voluntary representations of the performance of distribution transformers at conditions other than those required currently for compliance testing. DOE estimates that, if a manufacturer chose to make such representations, no additional testing cost would be incurred because the voluntary representations could be determined mathematically and without any additional testing required. Therefore, DOE concludes that no incremental testing cost and no additional testing burden would be incurred by manufacturers because of this proposed rule.

Given that the proposed test procedures would not increase burden on small manufacturers, DOE certifies that the proposed testing procedure amendments would not have a ''significant economic impact on a substantial number of small entities,'' and the preparation of an IRFA is not warranted. DOE will submit a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

DOE seeks comment on whether the proposed test procedure changes would place new and significant burdens on a substantial number of small entities.

D. Review Under the Paperwork Reduction Act of 1995

Manufacturers of distribution transformers must certify to DOE that their products comply with any applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their products according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including distribution transformers. (See generally 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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

E. Review Under the 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 rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

F. Review Under the National Environmental Policy Act of 1969

In this proposed rule, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for distribution transformers. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this proposed rule would amend the existing test procedures without affecting the amount, quality or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

G. Review Under 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. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

H. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following

requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 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 proposed rule meets the relevant standards of Executive Order 12988.

I. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

J. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988) that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under 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 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.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of distribution transformers is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

M. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The proposed modifications to the test procedure for distribution transformers in this NOPR do not incorporate by reference any commercial testing standards. Therefore, the requirements of section 32(b) of the FEAA do not apply.

N. Referenced Consensus Standards

In this NOPR, DOE does not propose to incorporate by reference any industry test standards. Rather, DOE proposes that the test procedure continue to be stand-alone, and be based on NEMA TP 2–1998 and NEMA TP 2–2005, and the latest versions of the IEEE standards, IEEE C57.12.90–2015, IEEE C57.12.91–2011, IEEE C57.12.00–2015, and IEEE C57.12.01–2015.

V. Public Participation

A. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this notice.

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

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

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

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

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

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

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

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

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

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

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

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of this process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process should contact Appliance and Equipment Standards Program staff at (202) 586–6636 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

B. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1.) DOE requests comment on: (1) Whether the current definition of rectifier transformer is sufficiently specific, (2) if not, what modifications would make it sufficiently specific, and (3) whether partial output phase shift, harmonic current tolerance, or other electrical properties may be used to reliably identify rectifier transformers.

(2.) DOE requests comment on: (1) Whether the current definition of drive transformer is sufficiently specific, (2) if not, what modifications would make it sufficiently specific, and (3) the level of technical similarity drive transformers bear to rectifier transformers.

(3.) DOE requests comment on its proposed definition of ''per-unit load'' and its proposal to consolidate the usage of various terms referring to less-than-full rated load to the single term ''per-unit load.''

(4.) DOE requests comment on its proposed definition of ''terminal.''

(5.) DOE requests comment on its proposed definition of ''auxiliary device,'' and whether certain components should be added or removed from the listed auxiliary devices and why. DOE also requests comment on whether it is appropriate to include functional component

designations as part of a definition of ''auxiliary device'' and, if so, which functions and why.

(6.) DOE requests comment on its proposed updated definition of ''low-voltage dry-type distribution transformer.''

(7.) DOE requests comment on its proposed updated definition of ''reference temperature.''

(8.) DOE requests comment on the proposed updates based on the latest version of the applicable IEEE standards for testing distribution transformers, and specifically regarding whether industry is already testing to the requirements of those IEEE standards.

(9.) DOE requests comment on the tentative determination that each of the proposals do not increase test cost or burden, and that they would not result in different measured values than the current test procedure.

(10.) DOE requests comment on the proposal to amend the DOE test procedure to permit manufacturers to make voluntary representations at any additional PUL and/or reference temperature, and whether this would assist consumers in making better purchasing decisions based on their specific installation conditions. DOE requests comment on whether the current DOE test procedure would be appropriate at non-mandatory PULs and reference temperatures.

(11.) DOE requests comment on secondary winding configurations. DOE also requests comment on the magnitude of the additional losses associated with the less efficient configurations as well as the relative period of operation in each winding configuration.

(12.) DOE requests comments regarding when, or at what number of time constants, stability is reached for the voltmeter-ammeter method and the resistance bridge method.

(13.) DOE seeks comment on its proposal to maintain the laboratory ambient and transformer internal temperature requirements with no changes.

(14.) DOE seeks comment on its proposal to modify section 4.1 of appendix A to read ''. . .Test all distribution transformers using a sinusoidal waveform (k=1).''

(15.) DOE requests comment on its understanding of the impact and associated costs of the proposed test procedure. To the extent commenters believe that manufacturers would not be able to rely on data generated under the current test procedure should the proposed amendments be finalized, DOE requests comment on the potential associated costs.

(16.) DOE seeks comment on the degree to which the DOE test procedure should consider and be harmonized further with the most recent relevant industry standards for distribution transformers, and whether any changes to the Federal test method would provide additional benefits to the public. DOE also requests comment on the benefits and burdens of adopting any industry/voluntary consensus-based or other appropriate test procedure, without modification.

(17.) DOE seeks comment on whether the proposed test procedure changes would place new and significant burdens on a substantial number of small entities.

VI. Approval of the Office of the Secretary

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

List of Subjects in 10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation test procedures, Incorporation by reference, and Reporting and recordkeeping requirements.

Signed in Washington, DC, on April 23, 2019.

Steven Chalk,

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

For the reasons stated in the preamble, DOE is proposing to amend part 431 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Section 431.192 is amended by revising the definitions of *Low-voltage dry-type distribution transformer* and *Reference temperature,* and adding in alphabetical order, definitions for *Auxiliary device, Per-unit load,* and *Terminal,* to read as follows:

§ 431.192 Definitions.

* * * * *

Auxiliary device means a localized component of a distribution transformer that is a circuit breaker, switch, fuse, or surge/lightning arrester.

* * * * *

Low-voltage dry-type distribution transformer means a distribution transformer that—

(1) Has an input voltage of 600 volts or less;

(2) Is air-cooled; and

(3) Does not use insulating liquid as a coolant.

* * * * *

Per-unit load means the fraction of rated load.

* * * * *

Reference temperature means the temperature at which the transformer losses are determined, and to which such losses are corrected if testing is done at a different point. (Reference temperature values are specified in the test method in appendix A to this subpart.)

* * * * *

Terminal means a conducting element of a distribution transformer providing electrical connection to an external conductor that is not part of the transformer.

* * * * *

■ 3. Section 431.193 is revised to read as follows:

§ 431.193 Test procedures for measuring energy consumption of distribution transformers.

The test procedures for measuring the energy efficiency of distribution transformers for purposes of EPCA are specified in appendix A to this subpart. The test procedures specified in appendix A to this subpart apply only to distribution transformers subject to energy conservation standards at § 431.196.

■ 4. Section 431.196 is amended by revising the Notes in paragraphs (a)(1), (a)(2), (b)(1), (b)(2), (c)(1), and (c)(2), to read as follows:

§ 431.196 Energy conservation standards and their effective dates.

(a) * * *

(1) * * *

Note: All efficiency values are at 35 percent per-unit load.

(2) * * *

Note: All efficiency values are at 35 percent per-unit load.

(b) * * *

(1) * * *

Note: All efficiency values are at 50 percent per-unit load.

(2) * * *

Note: All efficiency values are at 50 percent per-unit load.

(c) * * *

(1) * * *

Note: All efficiency values are at 50 percent per-unit load.

(2) * * *

Note: All efficiency values are at 50 percent per-unit load.

* * * * *

■ 5. Appendix A to subpart K of part 431 is amended by:
■ a. Revising section 2.0;
■ b. Adding sections 2.1, 2.2, and 2.3;
■ c. Revising paragraph (b) and adding paragraph (c) in section 3.1;
■ d. Revising section 3.2.1.1;
■ e. Revising paragraph (b) of section 3.2.1.2;
■ f. Revising section 3.2.2;
■ g. Revising section 3.3;
■ h. Revising paragraphs (a) introductory text and paragraph (b) in section 3.3.2;
■ i. Revising section 3.3.3;
■ j. Revising the introductory text and adding paragraphs (f), (g), (h), and (i) in section 3.4.1;
■ k. Revising paragraph (a) in section 3.4.2;
■ l. Revising paragraph (a) in section 3.5;
■ m. Revising section 4.1;
■ n. Revising paragraph (a) and adding paragraph (c) in section 4.3;
■ o. Revising paragraph (b) and the note following the paragraph in section 4.4.2;
■ p. Revising section 4.4.3.3;
■ q. Revising section 5.1;
■ r. Revising section 6.0;
■ s. Revising section 6.1;
■ t. Revising paragraph (a) of section 6.2; and
■ u. Adding section 7.0.

The additions and revisions read as follows:

Appendix A to Subpart K of Part 431—Uniform Test Method for Measuring the Energy Consumption of Distribution Transformers

* * * * *

2.0 Per-Unit Load, Reference Temperature, and Accuracy Requirements

2.1 Per-unit Load

In conducting the test procedure in this Appendix for the purpose of:

(a) Certification to an energy conservation standard, the applicable per-unit load in Table 2.1 must be used; or

(b) Making voluntary representations as provided in section 7.0 at an additional per-unit load, select the per-unit load of interest.

TABLE 2.1—PER-UNIT LOAD FOR CERTIFICATION TO ENERGY CONSERVATION STANDARDS

Distribution transformer category	Per-unit load (percent)
Liquid-immersed	50
Medium-voltage dry-type	50
Low-voltage dry-type	35

2.2 Reference Temperature

In conducting the test procedure in this Appendix for the purpose of:

(a) Certification to an energy conservation standard, the applicable reference temperature in Table 2.2 must be used; or

(b) Making voluntary representations as provided in section 7.0 at an additional reference temperature, select the reference temperature of interest.

TABLE 2.2—REFERENCE TEMPERATURE FOR CERTIFICATION TO ENERGY CONSERVATION STANDARDS

Distribution transformer category	Reference temperature
Liquid-immersed	20 °C for no-load loss. 55 °C for load loss.
Medium-voltage dry-type	20 °C for no-load loss. 75 °C for load loss.
Low-voltage dry-type	20 °C for no-load loss. 75 °C for load loss.

2.3 Accuracy Requirements

(a) Equipment and methods for loss measurement must be sufficiently accurate that measurement error will be limited to the values shown in Table 2.3.

TABLE 2.3—TEST SYSTEM ACCURACY REQUIREMENTS FOR EACH MEASURED QUANTITY

Measured quantity	Test system accuracy
Power Losses	±3.0%.
Voltage	±0.5%.
Current	±0.5%.
Resistance	±0.5%.
Temperature	±1.5 °C for liquid-immersed distribution transformers, and ±2.0 °C for low-voltage dry-type and medium-voltage dry-type distribution transformers.

(b) Only instrument transformers meeting the 0.3 metering accuracy class, or better, may be used under this test method.

3.0 * * *

3.1 General Considerations

* * * * *

(b) Measure the direct current resistance (R_{dc}) of transformer windings by one of the methods outlined in section 3.3. The methods of section 3.5 must be used to correct load losses to the applicable reference temperature from the temperature at which they are measured. Observe precautions while taking measurements, such as those in section 3.4, in order to maintain measurement uncertainty limits specified in Table 2.3.

(c) Measure resistance with the transformer energized by a 60 Hz supply.

* * * * *

3.2.1.1 Methods

Record the winding temperature (T_{dc}) of liquid-immersed transformers as the average of either of the following:

(a) The measurements from two temperature sensing devices (for example, thermocouples) applied to the outside of the transformer tank and thermally insulated from the surrounding environment, with one located at the level of the insulating liquid and the other located near the tank bottom or at the lower radiator header if applicable; or

(b) The measurements from two temperature sensing devices immersed in the insulating liquid, with one located directly above the winding and other located directly below the winding.

3.2.1.2 Conditions

* * * * *

(b) The temperature of the insulating liquid has stabilized, and the difference between the top and bottom temperature does not exceed 5 °C. The temperature of the insulating liquid is considered stable if the top liquid temperature does not vary more than 2 °C in a 1-h period.

3.2.2 Dry-Type Distribution Transformers

Record the winding temperature (T_{dc}) of dry-type transformers as one of the following:

(a) For ventilated dry-type units, use the average of readings of four or more thermometers, thermocouples, or other suitable temperature sensors inserted within the coils. Place the sensing points of the measuring devices as close as possible to the winding conductors; or

(b) For sealed units, such as epoxy-coated or epoxy-encapsulated units, use the average of four or more temperature sensors located on the enclosure and/or cover, as close to different parts of the winding assemblies as possible; or

(c) For ventilated units or sealed units, use the ambient temperature of the test area, only if the following conditions are met:

(1) All internal temperatures measured by the internal temperature sensors must not differ from the test area ambient temperature by more than 2 °C.

Enclosure surface temperatures for sealed units must not differ from the test area ambient temperature by more than 2 °C.

(2) Test area ambient temperature must not have changed by more than 3 °C for 3 hours before the test.

(3) Neither voltage nor current has been applied to the unit under test for 24 hours. In addition, increase this initial 24-hour period by any added amount of time necessary for the temperature of the transformer windings to stabilize at the level of the ambient temperature. However, this additional amount of time need not exceed 24 hours (*i.e.,* after 48 hours, the transformer windings can be assumed to have stabilized at the level of the ambient temperature. Any stabilization time beyond 48 hours is optional).

3.3 Resistance Measurement Methods

Make resistance measurements using either the resistance bridge method (section 3.3.1), the voltmeter-ammeter method (section 3.3.2) or resistance meters (section 3.3.3). In each instance when this Appendix is used to test more than one unit of a basic model to determine the efficiency of that basic model, the resistance of the units being tested may be determined from making resistance measurements on only one of the units.

* * * * *

3.3.2 Voltmeter-Ammeter Method

(a) Employ the voltmeter-ammeter method only if the test current is limited to 15 percent of the winding current. Connect the transformer winding under test to the circuit shown in Figure 3.3. * * *

(b) To perform the measurement, turn on the source to produce current no larger than 15 percent of the rated current for the winding. Wait until the current and voltage readings have stabilized and then take a minimum of four readings of voltage and current. Voltage and current readings must be taken simultaneously for each of the readings. Calculate the average voltage and average current using the readings. Determine the winding resistance R_{dc} by using equation 3–4 as follows:

$$R_{dc} = (V_{mdc}/I_{mdc}) \qquad (3\text{-}4)$$

Where:

V_{mdc} is the average voltage measured by the voltmeter V, and

I_{mdc} is the average current measured by the ammeter (A).

* * * * *

3.3.3 Resistance Meters

Resistance meters may be based on voltmeter-ammeter, or resistance bridge, or some other operating principle. Any meter used to measure a transformer's winding resistance must have specifications for resistance range, current range, and ability to measure highly inductive resistors that cover the characteristics of the transformer being tested. Also, the meter's specifications for accuracy must meet the applicable criteria of Table 2.3 in section 2.3.

* * * * *

3.4.1 Required Actions

The following requirements must be observed when making resistance measurements:

* * * * *

(f) Keep the polarity of the core magnetization constant during all resistance measurements.

(g) For single-phase windings, measure the resistance from terminal to terminal. The total winding resistance is the terminal-to-terminal measurement. For series-parallel windings, the total winding resistance is the sum of the series terminal-to-terminal section measurements.

(h) For wye windings, measure the resistance from terminal to terminal or from terminal to neutral. For the total winding resistance, the resistance of the lead from the neutral connection to the neutral bushing may be excluded. For terminal-to-terminal measurements, the total resistance reported is the sum of the three measurements divided by two.

(i) For delta windings, measure resistance from terminal to terminal with the delta closed or from terminal to terminal with the delta open to obtain the individual phase readings. The total winding resistance is the sum of the three-phase readings if the delta is open. If the delta is closed, the total winding resistance is the sum of the three phase-to-phase readings times 1.5.

3.4.2 Guideline for Time Constant

(a) The following guideline is suggested for the tester as a means to facilitate the measurement of resistance in accordance with the accuracy requirements of section 2.3:

* * * * *

3.5 Conversion of Resistance Measurements

(a) Resistance measurements must be corrected from the temperature at which the winding resistance measurements were made, to the reference temperature.

* * * * *

4.0 * * *

4.1 General Considerations

The efficiency of a transformer is computed from the total transformer losses, which are determined from the measured value of the no-load loss and load loss power components. Each of these two power loss components is measured separately using test sets that are identical, except that shorting straps are added for the load-loss test. The measured quantities need correction for instrumentation losses and may need corrections for known phase angle errors in measuring equipment and for the waveform distortion in the test voltage. Any power loss not measured at the applicable reference temperature must be adjusted to that reference temperature. The measured load loss must also be adjusted to a specified output loading level if not measured at the specified output loading level. Test all distribution transformers using a sinusoidal waveform (k=1). Measure losses with the transformer energized by a 60 Hz supply.

* * * * *

4.3 Test Sets

(a) The same test set may be used for both the no-load loss and load loss measurements provided the range of the test set encompasses the test requirements of both tests. Calibrate the test set to national standards to meet the tolerances in Table 2.3 in section 2.3. In addition, the wattmeter, current measuring system and voltage measuring system must be calibrated separately if the overall test set calibration is outside the tolerance as specified in section 2.3 or the individual phase angle error exceeds the values specified in section 4.5.3.

* * * * *

(c) Both load loss and no-load loss measurements must be made from terminal to terminal.

* * * * *

4.4.2 No-Load Loss Test

* * * * *

(b) Adjust the voltage to the specified value as indicated by the average-sensing voltmeter. Automatically and simultaneously record the values of rms voltage, rms current, electrical power, and average voltage using a digital data acquisition system. For a three-phase transformer, take all of the readings on one phase before proceeding to the next, and record the average of the three rms voltmeter readings as the rms voltage value.

Note: When the tester uses a power supply that is not synchronized with an electric utility grid, such as a dc/ac motor-generator set, check the frequency and maintain it within ±0.5 percent of the rated frequency of the transformer under test. A power source that is directly connected to, or synchronized with, an electric utility grid need not be monitored for frequency.

* * * * *

4.4.3.3 Correction of No-Load Loss to Reference Temperature

After correcting the measured no-load loss for waveform distortion, correct the loss to the reference temperature. For both certification to energy conservation standards and voluntary representations, if the correction to reference temperature is applied, then the core temperature of the transformer during no-load loss measurement (T_{nm}) must be determined within ±10 °C of the true average core temperature. For certification to energy conservation standards only, if the no-load loss measurements were made between 10 °C and 30 °C, this correction is not required. Correct the no-load loss to the reference temperature by using equation 4–2 as follows:

$$P_{nc} = P_{nc1}[1 + 0.00065(T_{nm} - T_{nr})] \qquad (4\text{-}2)$$

Where:

P_{nc} is the no-load losses corrected for waveform distortion and then to the reference temperature,

P_{nc1} is the no-load losses, corrected for waveform distortion, at temperature T_{nm},

T_{nm} is the core temperature during the measurement of no-load losses, and

T_{nr} is the reference temperature.

* * * * *

5.0 * * *

5.1 Output Loading Level Adjustment

If the per-unit load selected in section 2.1 is different from the per-unit load at which the load loss power measurements were made, then adjust the corrected load loss power, P_{lc2}, by using equation 5–1 as follows:

$$P_{lc} = P_{lc2}\left[\frac{P_{os}}{P_{or}}\right]^2 = P_{lc2}L^2 \qquad (5\text{-}1)$$

Where:

P_{lc} is the adjusted load loss power to the per-unit load,

P_{lc2} is as calculated in section 4.5.3.3,

P_{or} is the rated transformer apparent power (name plate),

P_{os} is the adjusted rated transformer apparent power, where $P_{os} = P_{or}L$, and

L is the per-unit load, *e.g.,* if the per-unit load is 50 percent then ''L'' is 0.5.

* * * * *

6.0 Test Equipment Calibration and Certification

Maintain and calibrate test equipment and measuring instruments, maintain calibration records, and perform other test and measurement quality assurance procedures according to the following sections. The calibration of the test set must confirm the accuracy of the test set to that specified in section 2.3, Table 2.3.

6.1 Test Equipment

The party performing the tests must control, calibrate and maintain measuring and test equipment, whether or not it owns the equipment, has the equipment on loan, or the equipment is provided by another party. Equipment must be used in a manner which assures that measurement uncertainty is known and is consistent with the required measurement capability.

6.2 Calibration and Certification

* * * * *

(a) Identify the measurements to be made, the accuracy required (section 2.3) and select the appropriate measurement and test equipment;

* * * * *

7.0 Test Procedure for Voluntary Representations

Follow sections 1.0 through 6.0 of this appendix using the per-unit load and/or reference temperature of interest for voluntary representations of efficiency, and corresponding values of load loss and no-load loss at additional per-unit load and/or reference temperature. Representations made at a per-unit load and/or reference temperature other than those required to comply with the energy conservation standards at § 431.196 must be in addition to, and not in place of, a representation at the required DOE settings for per-unit load and reference temperature. As a best practice, the additional settings of per-unit load and reference temperature should be provided with the voluntary representations.

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Centers for Medicare & Medicaid Services

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Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 403

[CMS–4187–F]

RIN 0938–AT87

Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Federal Health Insurance Programs for the Aged and Disabled by amending regulations for the Medicare Parts A, B, C and D programs, as well as the Medicaid program, to require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC or list price) of that drug or biological product. This rule is intended to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize their out-of-pocket (OOP) costs and expenditures borne by Medicare and Medicaid, both of which are significant problems.

DATES: This rule is effective July 9, 2019.

FOR FURTHER INFORMATION CONTACT: Cheri Rice, (410) 786–6499.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Purpose and Statutory Basis

Delivering better care at more transparent, lower prices is one way the Trump Administration is putting American patients first. The May 2018 Trump Administration blueprint to lower drug prices described a new, more transparent drug pricing system that would lower high prescription drug prices and bring down out-of-pocket (OOP) costs. The blueprint described four strategies: Boosting competition, enhancing negotiation, creating incentives for lower list prices, and reducing OOP spending.

The blueprint called for HHS to consider requiring the inclusion of list prices in direct-to-consumer (DTC) advertising. This final rule will improve the efficient administration of the Medicare and Medicaid programs by improving drug price transparency and informing consumer decision-making, both of which can increase price competition and slow the growth of federal spending on prescription drugs.

B. Summary of the Rule

In the October 18, 2018 **Federal Register** (83 FR 52789), we published a proposed rule titled ''Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency'' (hereinafter referred to as the ''October 2018 proposed rule''). After consideration of the public comments received, we are finalizing this rule largely as proposed, with one modification to proposed § 403.1204(b) in response to comments, and other minor technical changes to improve clarity.

This final rule requires DTC television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product. This final rule amends subchapter A, part 403, by adding a new subpart L.

New § 403.1202 requires that advertisements for certain prescription drugs or biological products on television (including broadcast, cable, streaming, and satellite) contain a statement or statements indicating the Wholesale Acquisition Cost (referred to as WAC or the list price) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: ''The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.''

New § 403.1200 specifies that this requirement applies to any advertisement for a prescription drugs or biological product distributed in the United States, for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act, except for a prescription drugs or biological product that has a list price, as defined herein, of less than $35 per month for a 30-day supply or typical course of treatment. The list price stated in the advertisement must be current, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. When the typical course of treatment varies based on the indication for which the drug or biological product is prescribed, the list price should represent the typical course of treatment associated with the primary indication addressed in the advertisement. To the extent permissible under current laws, manufacturers are permitted to include an up-to-date list price of a competitor's product, so long as they do so in a truthful, non-misleading way.

New § 403.1203 specifies that the required list price disclosure set forth in § 403.1202 must be conveyed in a legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

Finally, new § 403.1204 specifies that the Secretary will maintain a public list that would include the prescription drugs and biological products advertised in violation of these requirements. We anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act sec. 43(a), 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising.

Accordingly, we proposed at § 403.1204(b) that this rule preempt any state-law-based claim that depends in whole or in part on any pricing statement required by this rule. No state or political subdivision of any state may establish or continue in effect any requirement that depends in whole or in part on any pricing statement required by these regulations.

C. Problems That This Rule Seeks To Address

1. Rising Prices and Costs and Their Effect on the Medicare and Medicaid Programs and Their Beneficiaries

(a) Rise in Prices and Costs

The cost of drugs and biological products over the past decade has increased dramatically, and prices are projected to continue to rise faster than overall health spending, thereby increasing this sector's share of health care spending. The HHS Office of the Assistant Secretary for Planning and Evaluation estimates that prescription drug spending in the United States was about $457 billion in 2015, or 16.7 percent of overall personal health care services. Of that $457 billion, $328 billion (71.9 percent) was for retail drugs and $128 billion (28.1 percent) was for non-retail drugs. Factors underlying the rise in prescription drug spending from 2010 to 2014 can be roughly allocated as follows: 10 percent of that rise was due to population growth; 30 percent to an increase in prescriptions per person; 30 percent to overall, economy-wide inflation; and 30 percent to either changes in the composition of drugs prescribed toward higher price products or price increases for drugs that together drove average price increases in excess of general inflation.[1]

This final rule is designed to address rising list prices by introducing price transparency that will help improve the efficiency of Medicare and Medicaid programs by reducing wasteful and abusive increases in drug and biological product list prices—spiraling drug costs that are then passed on to federal healthcare program beneficiaries and American taxpayers more broadly. First, it will provide manufacturers with an incentive to reduce their list prices by exposing overly costly drugs to public scrutiny. Second, it will provide some consumers with more information to better position them as active and well-informed participants in their health care decision-making. Consumers make a series of critical health care decisions related to their treatment with prescription drugs or biological products, and the list price of those drugs may inform those decisions. Even where the consumer may be insured, and therefore may be paying substantially less than the list price, the coinsurance borne by some consumers will increase as the WAC increases.

(b) Impact of Rise in Prices and Costs on Part B and Part D Beneficiaries

As discussed in the proposed rule, CMS is the single largest payor of prescription drugs in the nation. In 2017, CMS and its beneficiaries spent $224.6 billion ($166.2 billion net of rebates) on drug benefits provided under Part B ($30.6 billion),[2] Part D ($129.7 billion gross spend, $100.7 billion net of rebates),[3] and Medicaid ($64.0 billion gross spend, $34.9 billion net of rebates including federal and state funds).[4] An additional sum was spent on drugs furnished by hospitals under Part A's inpatient prospective payment system, but the precise amount is difficult to isolate because hospitals receive a single payment for all non-physician services provided during an inpatient stay (including drugs). In 2016, CMS and its beneficiaries spent more than $238 billion on prescription drugs, approximately 53 percent of the $448.2 billion spent on retail and non-retail prescription drugs in the United States that year. Each year overall expenditures on drugs by both the Medicare and Medicaid programs and their beneficiaries have increased at rates greater than inflation both in the aggregate and on a per beneficiary basis.[5] These dramatically increasing costs are a threat to the sustainability of the programs and harm CMS beneficiaries every day.

(c) Impact on States Under Medicaid—Rising Prices and Costs Adversely Affects Medicaid and Benefits Offered to Beneficiaries

The increasing cost of drugs and biological products are a major concern for state Medicaid agencies. The Medicaid and CHIP Payment and Access Commission (MACPAC) states that the ''[h]igh rates of spending growth for prescription drugs have been of great concern to state and federal Medicaid officials. In 2014, Medicaid prescription drug spending experienced its highest rate of growth in almost three decades. And although spending growth slowed in 2015 and 2016, over the next 10 years prescription drugs could see the fastest average annual spending growth of any major health care good or service due to growth in high-cost specialty drugs.'' [6] States are having to balance alternatives to control drug costs,[7] and increases in drug spending that threaten the provision of other health services are causing other states to address drug costs to keep their programs sustainable.[8] [9] [10]

2. Direct-to-Consumer Advertising

Prescription drugs, by definition, cannot be accessed directly by the consumer; they must be prescribed by a licensed health care practitioner. We know, however, that consumers are responsible for critical choices related to their treatment with prescription drugs. For example, consumers decide whether

[1] U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, *ASPE Issue Brief: Observations on Trends in Prescription Drug Spending,* (2016). *https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.*

[2] ASPE Calculations from Part B Standard Analytic Files.

[3] 2018 Annual Report of the Board of Trustees' of the Federal Hospital and Insurance and Federal Supplementary Medical Insurance Trust Funds.

[4] MACPAC. Fact Sheet: Medicaid Drug Spending Trends. Feb 2019. *https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf.*

[5] According to the 2018 Annual Report of the Board of Trustees' of the Federal Hospital and Insurance and Federal Supplementary Medical Insurance Trust Funds, over the past 10 years, Part D benefit payments have increased by an annual rate of 7.4 percent in aggregate and by 3.8 percent on a per enrollee basis. These results reflect the rapid growth in enrollment, together with multiple prescription drug cost and utilization trends that have varying effects on underlying costs. For example, though there has been a substantial increase in the proportion of prescriptions filled with low-cost generic drugs there has also been a significant increase in spending on high-cost specialty drugs (including those most frequently advertised via televised DTC advertisements), leading to overall increased costs. In other words, the per beneficiary cost of drugs through Part D has increased nearly 40% over the past decade, while the consumer price index has increased only 19% during this same period. Over the period 2013–2016, Medicare Parts D and B, and Medicaid expenditures on a per beneficiary basis increased by 22%, 32%, and 42% respectively. Drug price inflation accounts for some of this growth. Between 2006 and 2015, Part D brand drug prices rose by an average 66% cumulatively.

[6] MACPAC. Prescription Drugs. *https://www.macpac.gov/topics/prescription-drugs/.*

[7] Young K and Garfield R. Kaiser Family Foundation Issue Brief: Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control. Feb 2018, *http://files.kff.org/attachment/Issue-Brief-Snapshots-of-Recent-State-Initiatives-in-Medicaid-Prescription-Drug-Cost-Control.*

[8] Reck J. As Drug Prices Rise, Oklahoma's Medicaid Agency Advances Alternative Payment Models. National Academy for State Health Policy. 2018 Dec 17. *https://nashp.org/as-drug-prices-rise-oklahomas-medicaid-agency-advances-alternative-payment-models/.*

[9] Rosenberg T. Treat Medicines Like Netflix Treats Shows. NYT. *https://www.nytimes.com/2019/03/05/opinion/can-netflix-show-americans-how-to-cut-the-cost-of-drugs.html.*

[10] Gee R. Health Affairs Blog. Louisiana's Journey Toward Eliminating Hepatitis C. 2019 April 1. *https://www.healthaffairs.org/do/10.1377/hblog20190327.603623/full/.*

to make the initial appointment with a physician; whether to ask the physician about a particular drug or biological product; whether to fill a prescription; whether to take the drug; and whether to continue taking it in adherence to the prescribed regimen. Drug manufacturers, therefore, spend billions of dollars annually promoting their prescription drugs and biological products directly to consumers through television advertisements and other media.

In 2017, over $5.5 billion was spent on prescription drug advertising, including nearly $4.2 billion on television advertising.[11] DTC advertising appears to directly affect drug utilization.[12] DTC advertising may increase disease awareness and facilitate more informed discussions between consumers and their health care providers. But it can also result in increased utilization through patients requesting costly drugs and biological products seen on television. This could cause problematic increases in government spending if less costly alternatives are available, or would be available through market pressures resulting from greater price transparency.

(a) Direct-to-Consumer Advertising Promotes Interaction With Physicians, but Also Is a Factor in Increasing Demand for Higher Cost Drugs

Studies show that consumers exposed to drug advertisements can exert sufficient pressure on their physicians to prescribe the advertised product.[13] In one recent survey, 11 percent said they were prescribed a specific drug after asking a doctor about it as a result of seeing or hearing an advertisement.[14] Another study concludes that there is evidence that DTC advertising can lead to more physician visits, diagnoses, and prescriptions for advertised conditions, though there is little evidence showing that the additional care is medically necessary.[15] The same study found that DTC advertising is associated with higher prescribing volume of advertised drugs, increased patient demand, and a shift in prescribing behavior. Other studies have shown that DTC advertising increases both the utilization of pharmaceuticals [16] and costs of pharmaceuticals.[17]

(b) Physicians Lack Access to Published WAC Data or a Patient's Out-of-Pocket Costs

DTC advertising, which has been shown to increase prescribing and demand for high-cost drugs, currently provides no context for physicians and other prescribers to assess a drug's cost or compare the costs of different treatments. Although the WAC for most drugs payable under Medicare Part B is reported to CMS and the WAC for most other drugs is reported to commercial compendia for widespread use by pharmacies and payors, prescribers generally lack access to this information. In addition, prescribers generally lack information about a drug's formulary placement or the cost sharing that patients would pay. For this reason, in our recent proposed rule titled, ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' 83 FR 62152 (November 30, 2018), we proposed to require that Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's e-prescribing and electronic medical record systems, to make beneficiary-specific drug coverage and cost information visible to prescribers who wish to consider such information in their prescribing decisions. This could provide an important supplement to any pricing information that is provided to patients and allow both the patient and provider to be informed when having discussions about the best overall therapy for the patient.

3. Direct-to-Consumer Advertising That Lacks Meaningful Pricing Information Is Potentially Misleading

As we stated in the October 2018 proposed rule, price transparency has been lacking in the case of prescription drugs or biological products, where consumers often need to make decisions without information about a product's price. Price transparency is a necessary element of an efficient market that allows consumers to make informed decisions when presented with relevant information. However, for consumers of prescription drugs or biological products, including those whose drugs are covered through Medicare or Medicaid, both the list price and actual price to the consumer remain hard to find. Third-party payment, a dominant feature of health care markets, is not a prominent feature of other markets of goods and services and causes distortions, such as an absence of meaningful prices and the information and incentives those prices provide. Because of the confusion and distortions in the existing prescription drug market, it is our view that the absence of the WAC would make a DTC television advertisement potentially misleading because consumers appear to dramatically underestimate their OOP costs for expensive drugs, but once they learn the WAC, they become far better able to approximate their OOP costs.[18]

(a) Studies Suggest That Patients Are Ill-Informed About Their Out-of-Pocket Costs and Do Not Use Available Online Services

As we explain in further detail in section II.C.1 below, although the WAC is highly relevant to patients' OOP costs, it may not reflect what a patient actually pays. Studies show that many beneficiaries do not appropriately use existing online tools, such as the Medicare Part D Plan Finder, to find the most cost effective product [19] [20] or to determine their OOP costs. While we continue to believe that the Medicare Part D Plan Finder is very helpful and we hope more patients use it, we think the DTC advertisement disclosure provides additional information that is very useful to patients to help them understand drug pricing. In this context, the availability of readily accessible pricing data—such as what would be conveyed at the time a DTC

[11] Kantar Media Advertising Intelligence—2013 to 2017 Prescription Medications Ad Spend Data.

[12] Dave D and Saffer H. Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand, Southern Economic Journal. 79 (1), 97–126; Datti B and Carter MW. The Effect of Direct-to-Consumer Advertising on Prescription Drug Use by Older Adults, Drugs Aging. 2006;23(1):71–81.

[13] Mintzes B, Barer ML, Kravitz RL, et al. Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: Two site cross sectional survey, BMJ. 2002 Feb 2;324(7332):278–9.

[14] Kirzinger A, Wu B, and Brodie M. Kaiser Health Tracking Poll—June 2018: Campaigns, Pre-Existing Conditions, and Prescription Drug Ads. Jun 27, 2018. *https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-june-2018-campaigns-pre-existing-conditions-prescription-drug-ads/.*

[15] Mintzes B. Advertising of Prescription-Only Medicines to the Public: Does Evidence of Benefit Counterbalance Harm? Annu Rev Public Health. 2012 Apr;33:259–77.

[16] Frosch DL, Grande D, Tarn DM, Kravitz RL. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. Am J Public Health. 2010;100(1):24–32.

[17] Law MR, Soumerai SB, Adams AS, Majumdar SR. Costs and consequences of direct-to-consumer advertising for clopidogrel in Medicaid. Arch Intern Med. 2009 Nov 23;169(21):1969–74.

[18] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''JAMA 2019 Study'').

[19] Heiss F, Leive A, McFadden D, and Winter J. Plan selection in Medicare Part D: evidence from administrative data. J Health Econ. 2013 Dec;32(6):1325–44.

[20] Zhou C and Zhang Y. The vast majority of Medicare Part D beneficiaries still don't choose the cheapest plans that meet their medication needs. Health Aff. 2012 Oct;31(10):2259–65.

advertisement is aired—becomes more important.

(b) Studies Suggest That Patients Want to Know the List Price of Drugs

Despite the fact that a patient's OOP costs will likely differ from the list price, studies indicate that knowing the list price of a drug is important to consumers. A recent tracking poll by the Kaiser Family Foundation found that 88 percent of Americans support requiring drug manufacturers to include their list prices in DTC advertisements.[21] The same survey found that 24 percent of Americans find it difficult to afford their drugs, and 10 percent say that it is very difficult to afford their drugs. Of those that spend more than $100 per month on drugs, 58 percent find it difficult to afford their drugs. The poll showed broad support for policies intended to reduce prescription drug costs. The price disclosure requirements that we are finalizing in this rule will provide consumers with this important information needed to aid them in an effort to find lower cost alternatives, and improve the efficiency of Medicare and Medicaid.

(c) Studies Suggest That Patients Who Know the List Price of a Drug Are Better Informed About Their Out-of-Pocket Costs Than Those Who Are Not Informed of the List Price

A recent study strongly suggests that when told the price of pharmaceutical products, patients are better able to approximate their OOP costs.[22] In that study, published after the proposed rule was issued, researchers asked subjects to estimate their monthly OOP costs for a drug with a hypothetical price of $15,500 per month. When subjects were provided no information about price, they responded that their OOP costs would be, on average, $78 per month. This finding tends to support our belief that patients seem to underestimate the true cost of drugs advertised on television. However, when subjects were told the price, they more accurately determined their OOP costs at $2,787 or about 18 percent of the hypothetical price. The informed estimates were far closer to what one would expect to see paid at the pharmacy counter under most plans than the uninformed assessment of $78. This finding provides evidence that patients may adjust their expectations of cost if they received pricing information.

D. How the Rule Addresses These Problems-Transparency in Drug Pricing Promotes Competition and Lowers Prices by Informing Beneficiaries

Both Titles XVIII and XIX of the Social Security Act reflect the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures. *See, e.g.,* Sections 1842(b)(8) and (9), 1860D–4(c)(3), 1860D–4(c)(5)(H), 1866(j)(2)(A), 1893(g), 1902(a)(64), 1902(a)(65), 1936(b)(2). In order to enable consumers to make good health care choices, which will in turn improve the efficiency of the Medicare and Medicaid programs, it is critical that they understand the costs associated with various medications. This is especially important where consumers have cost sharing obligations that may be significant. As discussed above, DTC television advertisements that do not provide pricing information may contribute to rising drug prices. Consumers of pharmaceuticals are currently missing information that consumers of other products can more readily access, namely the list price of the product, which acts as a point of comparison when judging the reasonableness of prices offered for potential substitute products. In an age where price information is ubiquitous, the prices of pharmaceuticals remain shrouded and limited to those who subscribe to expensive drug price reporting services. Consumers may be able to obtain some pricing information by going online to the websites of larger chain pharmacies. However, there are several reasons consumers are not likely to do this. First, while consumers make many critical decisions that bring about the ultimate writing of the prescription—making the appointment, asking the doctor about particular drugs, etc.—the physician, rather than the patient, ultimately controls the writing of the prescription. Second, meaningful price shopping is further hindered because the average consumer receives no basic price information. Arming a beneficiary with basic price information will provide him or her with an anchor price or a reference comparison to be used when making decisions about therapeutic options. Triggering conversations about a particular drug or biological product and its substitutes may lead to conversations not only about price, but also efficacy and side effects, which in turn may cause both the consumer and the prescriber to consider the cost of various alternatives (after taking into account the safety, efficacy, and advisability of each treatment for the particular patient). Ultimately, providing consumers with basic price information may result in the selection of lesser cost alternatives, all else being equal relative to the patient's care.

To this end, this rule requires price transparency for drugs that are advertised on television. Price transparency can be an effective and appropriate way to influence behavior and improve market efficiency. Price transparency has the potential to influence patient behavior, as well as address our increasing health care costs. Additionally, price transparency has been identified as a low-risk intervention with the potential to reduce health care costs without directly regulating health care reimbursement systems.[23]

II. Summary of, Analysis of, and Response to Public Comments

We received 147 comments in response to the October 18, 2018 proposed rule (83 FR 52789). Stakeholders offered comments that addressed both high-level issues related to DTC advertising as well as our specific proposals and requests for comments. We extend our deep appreciation to the public for its interest in lower drug prices and increased price transparency, and the many comments that were made in response to our proposed policies. In some instances, the public comments offered were outside the scope of the proposed rule and will not be addressed in this final rule.

A. Secretary's Statutory Authority To Require List Prices in Direct-to-Consumer Advertising for Manufacturers Whose Drugs Are Payable Under Titles XVIII or XIX of the Social Security Act

We proposed to use our authority under sections 1102 and 1871 of the Social Security Act to require manufacturers to disclose their list prices in DTC television advertisements. We received comments on our use of these authorities. These comments, and our responses, follow.

Comment: Many commenters stated that the proposal is beyond the authority of CMS to promulgate these regulations under a reasonable interpretation of sections 1102 and 1871 of the Social Security Act, specifically

[21] Kirzinger A, Lopes L, We B, and Brodie M. KFF Health Tracking Poll—February 2019: Prescription Drugs. Kaiser Family Foundation. 2019 March 01. *https://www.kff.org/8c7d090/.*

[22] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''2019 JAMA Study'')

[23] Sinaiko AD and Rosenthal MB. Increased price transparency in health care—challenges and potential effects. N Engl J Med. 2011 Mar 10;364(10):891–4.

noting that neither statutory provision says anything about prescription drugs or biological products, their prices, or advertisements about them. A commenter stated that while CMS acknowledges that it is bound both by the purposes and means specified by Congress, the agency improperly tries to mix and match various ends and means from disparate Social Security Act provisions to essentially create a new statute that this rule would ''implement.'' Commenters stated that CMS's interpretation is unreasonable because sections 1102 and 1871 of the Social Security Act are general housekeeping statutes, not broad delegations of authority.

Response: We disagree with these comments. As discussed in the proposed rule, the Secretary has the authority to promulgate regulations as necessary for the efficient administration of Medicare and Medicaid. Although we acknowledge that neither section 1102 nor section 1871 of the Social Security Act specifically references prescription drugs or biological products, their prices, or advertisements, we nevertheless believe that requiring manufacturers to include list prices in DTC television advertisements is supported by the plain text of these statutes. Section 1102 requires the Secretary to ''make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he or she] is charged'' under the Social Security Act. Similarly, section 1871 requires the Secretary to ''prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [Title XVIII].'' By their terms, then, these provisions authorize regulations that the Secretary determines are necessary to administer these programs. These statutes do not impose a limit on the means, other than to say, in the case of section 1102, that they not be inconsistent with the Social Security Act.

We also disagree with the commenters who believe that our interpretation of sections 1102 and 1871 is unreasonable. These provisions confer broad discretion upon the Secretary to determine the regulations that are necessary to the efficient administration of the functions with which he or she is charged under the Social Security Act (in the case of section 1102), and the administration of Medicare (in the case of section 1871). Thus, the text of these statutes clearly indicates that they are intended to permit requirements that are necessary to achieve those aims. Medicare and Medicaid beneficiaries have access to significant amounts of information about their OOP drug costs, such as the Medicare Part D Plan Finder, which permits Medicare Part D enrollees to look up information about their expected costs. However, beneficiaries do not use Plan Finder to the extent necessary to promote price competition. We are imposing this disclosure requirement to enable beneficiaries to make more informed decisions, as this will promote transparency, efficiency, and the responsible use of federal funds, in particular the Medicare trust funds.

We further disagree with commenters who contended that we are ''mixing and matching'' ends and means to form a statutory basis for this rule. In the proposed rule, we stated that the rule uses means that Congress has generally endorsed—disclosures about drug prices—to advance an end that Congress endorsed—minimizing unreasonable expenditures—and thus there is a clear nexus between HHS's proposed actions and the Act. This statement was not intended to indicate that we believe we can piece together statutory authority from various sources; rather, it was intended to show only that the requirements we proposed are within the realm of what is necessary for the efficient administration of Medicare and Medicaid because they are consistent with other means Congress has authorized elsewhere in the Social Security Act.

We disagree that sections 1102 and 1871 are housekeeping statutes. A true housekeeping statute, such as 5 U.S.C. 301, relates to internal agency governance. In contrast, sections 1102 and 1871 provide broad rulemaking authority to carry out Medicare and Medicaid and have been cited as authority for a multitude of regulations to implement these programs. *See Thorpe* v. *Housing Authority of City of Durham,* 393 U.S. 268, 277 n.28 (1969) (''*Thorpe*'').

Comment: Commenters stated that the cases cited in the proposed rule did not support the agency's interpretation of these statutory authorities and that because the cases cited predate *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), they are the not the correct standard under which to assess the agency's interpretation of its statutory authorities. These commenters state that the agency's interpretation fails under the two-part *Chevron* test.

Response: We disagree with these comments. The cases we cited stand for the proposition that a grant of broad rulemaking authority permits regulations that are reasonably related to the purposes of the programs for which rulemaking is authorized, and that the Secretary has discretion to determine which rules are necessary. *See Mourning* v. *Family Publ'ns Servs., Inc.,* 411 U.S. 356, 369 (1973) (''*Mourning*''*); Thorpe,* 393 U.S. at 277 n.28; *Sid Peterson Mem'l Hosp.* v. *Thompson,* 274 F.3d 301, 313 (5th Cir. 2001); *Cottage Health Sys.* v. *Sebelius,* 631 F. Supp. 2d 80, 92 (D.D.C. 2009). Even the cases cited in which regulations were struck down support CMS's interpretation. For example, in *Food & Drug Administration* v. *Brown & Williamson Tobacco Corporation,* 519 U.S. 120 (2000), the Supreme Court instructed that an agency's power to regulate must be grounded in a valid grant of authority from Congress, viewed in context of the overall statutory scheme. Viewing the Medicare and Medicaid schemes as a whole, nothing prohibits the requirements we are finalizing in this rule. Instead, they are consistent with the overall statutory scheme under the Social Security Act given the clear nexus between this requirement and Congress's recognition throughout the Social Security Act of the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures. Similarly, *Colorado Indian River Tribes* v. *National Indian Gaming Commission,* 466 F.3d 134 (D.C. Cir. 2006), states that agencies are bound by Congress's ultimate purpose and the selected means, but in that case—similar to *Brown & Williamson*—the regulations at issue, though based on a general grant of rulemaking authority, were invalidated because they would have been inconsistent with the overall statutory scheme that called for class III gaming to be subject to state-tribal compacts rather than agency regulations.

We disagree that the cases cited in the proposed rule represent the incorrect standard under which to assess our interpretation of sections 1102 and 1871 or that this rule fails the two-part *Chevron* test. With respect to questions of statutory interpretation, ''considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer.'' *Chevron,* 467 U.S. at 844. *Chevron* sets forth a deferential two-step process to review an agency's construction of a statute which it administers. 467 U.S. at 842. First, if Congress has unambiguously spoken to the issue in question, the court must give effect to Congress's intent. *Id.* at 843. Second, if the statute

is silent or ambiguous, the court should accord deference to the agency's construction so long as it is reasonable. *Id.* at 843–44. This rule complies with the first step of the *Chevron* test because Congress did not directly speak to the question of requiring the disclosure of the list price in DTC television advertisements, and nothing in the text or structure of the Medicare statute prohibits this rule. At the same time, consistent with the second step of the *Chevron* test, this rule is a permissible interpretation of the Secretary's broad authority to regulate for the efficient administration of the Medicare and Medicaid programs. As noted above, *Mourning* and *Thorpe* hold that broad rulemaking authority permits regulations reasonably related to program purposes. While we acknowledge that Congress has, indeed, provided HHS with various specific authorities to address drug costs and reimbursement rates, it does not follow that the requirements we are finalizing in this final rule are unauthorized. Just because Congress has expressly authorized particular means of addressing drug costs in general by authorizing generics and biosimilars and by imposing a rebate system for Medicaid does not signify that all other reasonable means are foreclosed, particularly if the other means are not inconsistent with the Social Security Act. The commenter's argument does not consider plain language of the provisions of the Social Security Act at issue, which, as noted previously, authorize regulations as may be necessary for the efficient administration of Medicare and Medicaid, so long as they are not inconsistent with the Social Security Act. For the reasons described in the proposed rule, the regulations we are finalizing in this rule are necessary for the efficient administration of Medicare and Medicaid. The Social Security Act's prohibition of the Secretary from interfering in Part D negotiations does not make the price disclosure requirement inconsistent with the Social Security Act. Rather, the non-interference provision is not relevant to whether we may require list prices be transparent to beneficiaries. List prices already are known to payors and manufacturers, so simply requiring they be made known to beneficiaries has no bearing on payor-manufacturer negotiations.

Comment: Several commenters further stated that Congress's directive to CMS to operate the Medicare and Medicaid programs efficiently cannot reasonably be construed as giving CMS the authority to regulate prescription drug advertising and that if Congress intended for CMS to do so, it would have expressly given the agency that authority.

Response: We disagree that explicit authority for this particular regulation is needed, because Congress has explicitly directed the Secretary to operate the Medicare and Medicaid programs efficiently and has expressly authorized regulations necessary to that purpose, so long as they are not inconsistent with the Social Security Act. Promoting pricing transparency, and thus efficient markets, for drugs funded through those programs falls within the scope of the Secretary's mandate. As we stated in the proposed rule, there is a clear nexus between the requirement we are imposing in this final rule and the efficient administration of Medicare and Medicaid. The DTC disclosure requirement is simply a way to ensure transparency of information necessary to minimize unreasonable expenditures, which is an important purpose that Congress has recognized throughout Titles XVIII and XIX of the Social Security Act.

Comment: One commenter stated that Congress has prescribed other means to address the costs of prescription drugs and biological products through federal laws such as the Drug Price Competition and Patent Term Restoration Act of 1984 and the Biologics Price Competition and Innovation Act of 2009, and that if Congress intended for CMS to have this authority it would have given it explicitly to CMS. The commenter stated that Congress also has prescribed numerous, highly detailed methods to control prescription drug and biological product costs in Medicare and Medicaid, such as the Medicaid drug rebate statute, but has expressly prohibited CMS from interfering in negotiations in Medicare Part D, which means that Congress has addressed a course of conduct for the agency that does not permit CMS to regulate prescription drug and biological product prices outside of federal healthcare programs. This commenter stated that the disclosure requirement would undermine the purposes of Medicare and Medicaid by discouraging appropriate and medically necessary use of drugs (and not just ''waste'' as the proposed rule contends), which demonstrates that Congress did not empower the Secretary to adopt the DTC requirement as a cost-containment measure.

Response: We disagree with the contention that requiring a disclosure of the list price is a cost control. In implementing this rule, we are not regulating how a manufacturer sets its list price, which remains entirely in the manufacturer's control. As we stated in the proposed rule, in order to enable consumers to make informed health care choices, which can, in turn, improve the efficiency for the Medicare and Medicaid programs, it is critical that they understand the costs associated with various medications. If transparency in such pricing prompts a manufacturer to make the business decision to reduce the list price of overly costly drugs, it is a desired, but by no means a required, outcome. Instead, this rule provides Medicare and Medicaid beneficiaries with important information—namely, an anchor price—they can use to make informed decisions about their care, including whether the difference between the list price and what they actually pay out of pocket is reasonable. For this reason, as well as the reasons described above in section I.C.3. of this final rule, requiring the disclosure of the WAC improves the efficiency of both Medicare and Medicaid.

Finally, we disagree that this disclosure requirement is inconsistent with the purposes of Medicare and Medicaid. The Medicare program provides federally funded health insurance to the elderly and the disabled. Medicaid is a federal-state program that provides financial assistance to states to furnish medical care to needy individuals. As we stated in the proposed rule, there are numerous provisions in the Social Security Act in which Congress has recognized that Medicare and Medicaid should be operated in such a manner as to minimize unreasonable expenditures. Making sure beneficiaries understand the value of their benefits is fully consistent with this goal. Congress has acknowledged in provisions such as sections 1851 and 1860D–1(c), which require the Secretary to broadly disseminate information to Medicare beneficiaries and prospective Medicare beneficiaries on coverage options under Medicare Parts C and D, that the provision of information to promote an active, informed selection among coverage options is important. This final rule, which requires disclosure of information to promote beneficiaries' understanding of the value of their benefits and enable them to make more informed choices, is similarly consistent with the programs' purposes.

Comment: One commenter wrote that CMS is acting within its authority under sections 1102 and 1871 of the Social Security Act in proposing to require pricing information in DTC advertisements, as CMS has broad

latitude to issue regulations that advance the efficient administration of the Medicare and Medicaid programs.

Response: We agree, and we thank the commenter for the support.

Comment: One commenter specifically noted its belief that CMS lacks the authority to regulate broadcast, cable, streaming, and satellite communications.

Response: We disagree with this comment. First, this rule does not regulate broadcasting. Second, as noted previously, sections 1102 and 1871 authorize regulations as necessary for the efficient administration of Medicare and Medicaid, and for the reasons described elsewhere in this preamble, the requirements we are finalizing in this rule are both necessary to that purpose, and not inconsistent with the Social Security Act. We also note that current HHS regulations address broadcast advertisements. For example, we regulate marketing by Medicare Advantage and Part D plans, including via newspapers, magazines, television, radio, billboards, the internet, and social media. See 42 CFR 422.2260, 423.2260.

Comment: Several commenters stated that Congress has given the FDA the authority to regulate DTC advertisements, not CMS. Several commenters stated that while the FDA has the authority to regulate DTC advertisements, it does not have any specific authority to require the listing of prices. A commenter stated that CMS lacks authority to promulgate a rule that would require manufacturers to violate existing FDA statutory or regulatory requirements.

Response: The statutory authority to issue rules, whether under the Social Security Act or the Federal Food, Drug, and Cosmetic Act, rests with and can always be exercised by the Secretary, even if such authority has been delegated to the individual agencies. We take no position in this rule on whether FDA has the authority to require the listing of drug prices in DTC advertisements. Whether FDA possesses such authority is not dispositive of the question of CMS's authority to implement the disclosure requirement necessary for the efficient administration of Medicare and Medicaid. Indeed, given CMS's role as an agency that reimburses for drugs, it is appropriate that CMS impose the price disclosure requirement, as it is the Medicare and Medicaid programs that bear the cost of drugs with excessively high prices.

Comment: One commenter stated that CMS has not drawn a rational connection between its proposal and high drug prices and provides no explanation for subjecting only television advertisements to the proposal. As such, the commenter contended that the proposal is arbitrary and capricious.

Response: We disagree with this comment. As discussed in the proposed rule, HHS has concluded that the rule has a clear nexus to the Social Security Act. In numerous places in the Act, Congress recognized the importance of administering the Medicare and Medicaid programs in a manner that minimizes unreasonable expenditures. Efficient administration of both Medicare and Medicaid, therefore, encompasses federal efforts to achieve value for funds spent in the Medicare and Medicaid programs. The transparency required by the disclosure requirement will provide beneficiaries with relevant information about the costs of prescription drugs and biological products, so they can make informed decisions that minimize costs, both for themselves and the Medicare and Medicaid programs. As discussed above in section I.C.2 of this final rule, studies suggest that DTC advertising directly affects drug utilization and exerts pressure to prescribe. The list price disclosure requirement is rational because it will require the price information to be transmitted at the same time as the rest of the advertisement; thus, it will be a seamless and meaningful way to provide concurrent, important context (*i.e.,* the list price) in a way that is low-cost for the manufacturer, and low-burden—but high-impact—for affected beneficiaries. It is appropriate and rational to implement this policy for only television advertisements because television advertising makes up over two thirds of the DTC spend for pharmaceuticals.[24] Additionally, television is a universal medium widely watched by beneficiaries, and therefore it is an efficient and effective means to ensure beneficiaries are provided with appropriate information. Traditional television reaches about 87 percent of the adult population, with older adults spending the most time watching television (Age 50–64: 5 hours and 38 minutes per day; Age 65+: 6 hours and 55 minutes per day).[25]

[24] Schwartz LM and Woloshin S. Medical Marketing in the United States, 1997–2016. JAMA. 2019 Jan 1;321(1):80–96.

[25] The Nielsen Total Audience Report Q2 2018. *https://www.nielsen.com/content/dam/corporate/us/en/reports-downloads/2018-reports/q2–2018-total-audience-report.pdf.*

B. General Comments on Direct-to-Consumer Advertising

We received general comments on the merits of DTC advertising.

Comment: Many commenters recommended against allowing DTC advertising at all. Some commenters noted that DTC advertisements leads to longer, less efficient patient encounters and reduced patient confidence in prescribers' advice. Commenters also stated DTC advertising increases inappropriate prescribing and drives demand for products that patients may not need. Many other commenters stated that DTC advertisements provide an important source of patient education by increasing disease awareness and informing patients and caregivers about new treatments.

Response: Eliminating DTC advertising is outside of the scope of this rule. We agree that DTC advertisements can both drive utilization and provide a source of patient education, and we are implementing the list price disclosure requirement so as to provide additional information as a resource to educate and inform patients in a manner that can temper the increases in demand that DTC advertising causes.

Comment: Many commenters support including the list price of prescription drugs and biological products in DTC advertising as an important step toward providing price transparency in our health care system. Many commenters note that being aware of the price of goods is essential for an efficient and competitive market to work. Additionally, many commenters note that drug cost is an important concern for patients, and this information will be important to allow them to have a meaningful conversation with their providers to select the best, most cost-effective, and most appropriate overall therapy.

Response: We appreciate the support for our proposal, and we agree that requiring a list price in DTC television advertising will provide valuable new information for patients to empower them to engage with their providers and engage in their care decisions. We agree that pricing information is essential for creating a more transparent health care system and an important element in creating a free and competitive market that will allow patients to be engaged consumers.

C. Use of Wholesale Acquisition Cost as List Price

In the proposed rule, we sought comment on whether WAC is the amount that best reflects the list price

for the stated purposes of price transparency and comparison shopping.

Comment: A few commenters expressed concern that the WAC is not standardized or well-defined enough to serve as a meaningful price point. A few commenters noted that the WAC varies by National Drug Code (NDC) and requested clarification on which NDC would be used in determining the WAC to be included in advertisements.

Response: We disagree that the WAC is not standardized or well-defined. Congress defined WAC in section 1847A of the Social Security Act, and we are finalizing a definition in this rule that parallels the statutory definition. WAC has been used in Medicare Part B drug payment policy for more than a decade without significant concern that it is not a meaningful price point.[26] In Medicare Part D, the negotiated price is a function of pharmacy-level charges, which are typically expressed in network pharmacy contracts as a function of the WAC (*e.g.,* $((WAC \times 1.2) - 15\% + \$2.00)$). With respect to the commenters' request for clarification about NDCs, we note that the regulation requires the list price for a 30-day supply or typical course of treatment. To the extent an NDC reflects an amount of the manufacturer's product other than a 30-day supply or typical course of treatment, the manufacturer will need to use reasonable assumptions to determine the appropriate list price for a 30-day supply or typical course of treatment.

Comment: Several commenters supported the use of the WAC. One commenter noted that the WAC is a well understood price point that is defined in statute and applies to every drug, and that because it serves as a starting point for negotiating prices, it directly impacts patients' costs. A few commenters noted that the full WAC is paid by the uninsured and by beneficiaries with high deductibles. Others noted that patients could estimate their out of pocket costs from the WAC if they understand the percentage coinsurance of their coverage. A few noted that due to variation in other price points, it would be administratively burdensome for manufacturers to display any price other than the WAC and that the proposal is easy for manufacturers to comply with. A few commenters noted their belief that with the proposed cost variation disclaimer, the WAC is an appropriate price point to share in advertisements. Others noted that the WAC is primarily informative for single-source drugs, which make up the majority of DTC advertisements.

Response: We appreciate these commenters' support for the use of the WAC, and agree that it is an appropriate metric for disclosure in DTC television advertisements for the reasons commenters note. The WAC is the most commonly used benchmark in the pharmacy purchasing of drugs, which means that it is a single, manufacturer-published price that excludes rebates and discounts, and therefore is the closest metric we have to a generalizable list price that applies to all patients prior to the application of insurance coverage, making this an actual list price of the drug. While insurance coverage will affect what the patient pays OOP for the drug, as stated above the WAC is an important factor for determining the final price that patients will pay for the drug. Moreover, the WAC is a real price that manufacturers set for their drugs and share with various private price compilers such as Red Book, Medispan, and First DataBank. WAC publishers sell subscriptions to their compilations, allowing pharmacies and others willing to pay annual subscription fees to access current prices. For all of these reasons, the WAC is a relevant and important price point in the drug supply chain.

Comment: Several commenters recommended that additional or different information should be required in advertisements other than the WAC. Specifically, commenters requested that DTC advertisements include detail on what a patient may expect to pay out of pocket. One commenter recommended that advertisements include both the WAC and expected out of pocket costs. A few commenters recommended that advertisements include rebate, discount and formulary information as well as details for consumers to make a coinsurance calculation. One commenter noted that patients want information about what payment support options may be available to them. One commenter expressed concern that the proposed disclosure does not give patients information about what other drug options may be available. A few commenters recommended that advertisements include appropriate explanations of what the WAC means.

Response: We decline to require manufacturers to provide pricing information in addition to the WAC of the drug being advertised because this rule is targeted to providing the minimum amount of cost information that will allow a patient to engage in shared decision making with their prescriber. We also decline to require that DTC advertisements explain what the WAC means, as the required disclosure language refers to the ''list price,'' and does not the term WAC. Further, the rule is targeted to require disclosure of the most essential price information, but manufacturers may include additional information if they so choose, so long as the information does not obscure safety and effectiveness information.

Comment: One commenter requested clarification on whether standard manufacturer costs would be used if the proposal were applied to the inpatient setting.

Response: The requirement we are finalizing in this rule will require DTC television advertisements to disclose the WAC of any drug for which payment is available under Medicare or Medicaid, regardless of the care setting.

Comment: A few commenters expressed concern that for drugs that lack therapeutic alternatives, disclosure of the WAC will be irrelevant because patients do not have cheaper options to choose from.

Response: We disagree. Even if a drug does not have any cheaper therapeutic alternatives, it will be useful to the patient and his or her caregivers to know its list price, as it will inform the conversation about anticipated costs.

Comment: Many commenters agree that the WAC is the best price point to include in DTC television advertisements because it is a single, easily accessible metric created by manufacturers and available to wholesalers, and is the most common benchmark used in pharmacy purchasing and reimbursement. One commenter recommended using National Average Drug Acquisition Cost (NADAC), which is a CMS-published benchmark created through a national survey of actual invoices paid by retail pharmacies to wholesalers. The commenter suggested that it is more accurate, especially for generic drugs. One commenter noted that alternative price points are more relevant to what patients pay, such as the Federal Upper Limit (FUL) and the Maximum Allowable Cost (MAC), which reflect rebates and discounts provided by manufacturers. One commenter recommended against displaying the average wholesale price (AWP), average acquisition cost (AAC), or national average drug acquisition cost (NADAC).

Response: We appreciate the feedback on alternative metrics for the list price.

[26] The WAC is used in Part B in two ways. First, Medicare Part B pays 106 percent times the lesser of the Average Sales Price (ASP) or WAC. *See* Social Security Act sec. 1847A(b)(4). Second, when a new Part B drug or biological product comes to market and has no established ASP, the Secretary may use the drug's or biologic's WAC or methodologies in effect on November 1, 2003 to determine the Part B payment amount. *See* Social Security Act sec. 1847A(c)(4).

We agree with the commenters that the WAC is an appropriate metric to use as a list price because it is commonly used, easily available and manufacturer-developed. We appreciate the comments that noted that the WAC is not available for all drugs. However, not only is the WAC generally available for the overwhelming majority of drugs, but it is available for the more expensive drugs that are commonly advertised on television, as shown in Table 1. All drugs that are distributed through a wholesaler have a WAC, including all of the top 20 drugs that have the highest DTC advertising spending. While we agree that other price metrics may be useful, we decline to adopt any of these other metrics as alternatives because we believe the WAC is a better metric for purposes of the disclosure requirement. As noted previously, a manufacturer sets its WAC, and therefore readily knows the WAC for all of its advertised products. In addition, generic drugs are rarely advertised on television, so the NADAC, which tracks generic prices, is not only less relevant for purposes of this rule, but is also one step removed from information—WAC—that the manufacturer already has at hand.

1. WAC Is a Benchmark for Federal and Commercial Healthcare Programs

A drug's WAC has relevance as a benchmark in both federal and commercial health care programs. In the commercial sector, nearly half of all beneficiaries have high deductible plans including those with plans purchased on the Health Insurance Exchange under the Affordable Care Act.[27] An analysis of commercial health plans also determined that nearly half of all drug spending is subject to deductible or coinsurance.[28]

Under Medicare Part B, after meeting the annual $185 deductible, beneficiaries generally pay a 20 percent co-insurance for all items and services, including prescription pharmaceuticals. When a Medicare Part B drug is new, it may be reimbursed for a period of time based on its WAC rather than its ASP. After that time, Medicare pays for prescription drugs based on the ASP. Sixty percent of the top 50 Part B drugs by spending have an ASP that is less than 10 percent different from the WAC.

Medicare Part D allows beneficiaries to choose a private health plan offering prescription drug benefits, and these include a standalone prescription drug plan (PDP) for those with original Medicare or a Medicare Advantage plan that includes prescription drug coverage (MA–PD). In 2018, the majority of Part D enrollees had some form of deductible, and more than 70 percent of standalone Part D plans offered in 2019 included a deductible.[29] The top 10 PDPs by enrollment, which represents 81 percent of standalone PDP enrollment, all charge coinsurance rather than copayments for drugs on nonpreferred tiers, charging 32 percent to 50 percent of each prescription's negotiated price (which closely resembles the WAC).[30] All Part D plans may charge coinsurance for drugs on the specialty tier. As such, the overwhelming majority of Part D beneficiaries are exposed to OOP costs based on the negotiated price (which closely resembles the WAC).

Table 1 includes the 20 drugs with the highest television advertising expenditures during CY2016. The average WAC for these drugs is $3,473 (range: $189–$16,937.91) per month.

Two of the drugs are covered by Medicare Part B, which requires Medicare beneficiaries to pay a coinsurance equal to 20 percent of a drug's ASP-based payment allowance for physician-administered drugs. For the two Part B drugs, the ASP of the drug closely resembles the WAC, suggesting that a beneficiary who knows the drug's WAC can easily approximate their OOP costs.

Eighteen of the drugs are covered by Medicare Part D, in which a beneficiary's OOP spending is dependent on the plan benefit design. For these 18 Part D drugs, the mean per month WAC was $3,586.44. We used the benefit design of the two PDPs with the lowest and highest premiums available to a Medicare beneficiary in Washington, DC, to estimate the formulary coverage and OOP costs for these 18 drugs. In the low-premium plan, all 18 drugs were subject to a deductible, during which time the beneficiary pays the negotiated price until entering the next phase of the benefit, seven (39 percent) were on the preferred tier and subject to a copayment after meeting the deductible, six (33 percent) were on the non-preferred or specialty tier and subject to coinsurance after meeting the deductible, and five (27 percent) were non-formulary drugs for which no insurance benefit is available (unless the beneficiary obtains a formulary exception). Thus, OOP spending was based on the WAC for all of the drugs before meeting the deductible, and 61 percent of the drugs after meeting the deductible. In the high-premium plan, all 18 drugs were subject to a deductible, during which time the beneficiary pays the negotiated price until entering the next phase of the benefit, five (27 percent) were on the preferred tier and subject to a copayment after meeting the deductible, eight (33 percent) were on the non-preferred or specialty tier and subject to coinsurance after meeting the deductible, and five (27 percent) were non-formulary drugs for which no insurance benefit is available (unless the beneficiary obtains a formulary exception). Thus, OOP spending was based on the WAC for all of the drugs before meeting the deductible, and 61 percent of the drugs after meeting the deductible. Of note, the WAC was often less than the Part D plan's negotiated price, and the high-premium plan subjected beneficiaries to coinsurance more often than the low-premium plan for the drugs with the highest DTC ad spending.

Thus, when drugs are purchased early in the year before a deductible has been met, or during the plan year when coinsurance applies, or at any time when a drug is not covered by insurance, the patient often pays the WAC or cost-sharing based on the WAC, making the WAC highly relevant. Knowing the WAC may also help a beneficiary begin a conversation about less expensive alternatives, prompt them to ask their pharmacist if a lower-cost option would be available, or encourage them to choose a plan with more favorable cost-sharing requirements.

[27] Cohen R, Martinez M, and Zammitte E. Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, January–March 2018. National Center for Health Statistics. *https://www.cdc.gov/nchs/data/nhis/earlyrelease/Insur201808.pdf.*

[28] Rae M, Cox C, and Sawyer B. What are recent trends and characteristics of workers with high drug spending? Peterson-Kaiser Health System Tracker. *https://www.healthsystemtracker.org/chart-collection/recent-trends-characteristics-workers-high-drug-spending-2016/#item-deductibles-and-coinsurance-represent-a-larger-share-of-out-of-pocket-drug-spending-than-a-decade-ago.*

[29] MedPAC Report to the Congress: Medicare Payment Policy. March 2019.

[30] MedPAC Report to the Congress: Medicare Payment Policy. March 2019.

TABLE 1—COMPARISON OF LIST PRICE AND OUT OF POCKET COST UNDER HIGH AND LOW PREMIUM PLANS FOR THE DRUGS WITH THE HIGHEST DTC ADVERTISING EXPENDITURES

Drug (quantity)	WAC per month	Representative low premium plan					Representative high premium plan				
		Tier	Negotiated price and deductible	Initial coverage	Coverage gap	Catastrophic	Tier	Negotiated price and deductible	Initial coverage	Coverage gap	Catastrophic
Humira (2 pens)	$5,174	Specialty	$5,169	$1,292	$1,292	$258	Specialty	$5,097	$1,325	$1,274	$255
Lyrica (60 tabs)	468	Preferred Brand	446	40	117	23	Preferred Brand	462	42	115	23
Xeljanz (60 tabs)	4,481	Specialty	4,477	1,119	1,119	224	Non-formulary	5,377	5,377	5,377	5,377
Trulicity (4 pens)	730	Preferred Brand	730	40	182	36	Nonpreferred Drug	720	345	180	36
Xarelto (30 tabs)	448	Preferred Brand	448	40	112	22	Preferred Brand	442	42	110	22
Otezla (60 tabs)	3,398	Non-formulary	4,078	4,078	4,078	4,078	Non-formulary	4,078	4,078	4,078	4,078
Eliquis (60 tabs)	444	Preferred Brand	444	40	111	22	Preferred Brand	438	42	110	22
Keytruda	4,719	Part B									
Ibrance (30 tabs)	16,938	Specialty	17,608	4,402	4,402	880	Specialty	16,686	4,338	4,171	834
Jardiance (30 tabs)	493	Preferred Brand	493	40	123	25	Preferred Brand	486	42	66	24
Rexulti (30 tabs)	1,109	Specialty	1,109	277	277	55	Nonpreferred Drug	1,093	525	273	55
Taltz (1 pen)	5,162	Non-formulary	6,442	6,442	6,442	6,442	Non-formulary	6,194	6,194	6,194	6,194
Verzenio (60 tabs)	12,087	Specialty	12,510	3,128	3,128	626	Nonpreferred Drug	11,907	5,715	2,977	595
Prevnar-13	189	Part B									
Eucrisa (1 tube)	633	Non-formulary	745	745	745	745	Non-formulary	745	745	745	745
Latuda (30 tabs)	1,223	Nonpreferred Drug	1223	562	306	61	Nonpreferred Drug	1,200	528	300	60
Victoza (3 pens)	922	Preferred Brand	921	40	230	46	Preferred Brand	908	42	227	45
Farxiga (30 tabs)	492	Preferred Brand	492	40	123	25	Nonpreferred Drug	486	233	121	24
Enbrel (4 pens)	5,174	Non-formulary	6,209	6,209	6,209	6,209	Specialty	5,097	1,325	1,274	255
Cosentyx (1 pen)	5,179	Non-formulary	4,661	4,661	4,661	4,661	Non-formulary	4,661	4,661	4,661	4,661

Note: In Table 1, we looked at the Top 20 drugs with the highest television advertising expenditures during CY 2016, per Kantar Media. We filled out the WAC for each of the drugs based on the common monthly package size using Analysource and ProspectoRx data. Then, we selected the plan in the Washington DC area (Zip 20201) that had the lowest monthly premium (WellCare Value Script (PDP)—$14 monthly premium) and a choice plan with the highest monthly premium (Express Scripts Medicare (PDP)—Choice—$97.20 monthly premium). We identified the tiers for the drugs based on the respective formularies for each plan. Then, we used the Plan Finder website for each plan to identify the deductible and initial coverage for each drug to estimate the OOP costs for beneficiaries before they enter catastrophic coverage phase. The WAC was obtained from Analysource and ProspectoRx data. Tiering info was obtained from Express Scripts Medicare Choice PDP 2019 Formulary and WellCare Value Script PDP 2019 Formulary. Deductible and Initial Coverage Period for Value Plan (WellCare Value Script (PDP)) OOP amounts were obtained from the Medicare.gov Part D Planfinder for an applicable beneficiary living in Washington DC (20201). Deductible and Initial Coverage Period for Choice Plan (Express Scripts Medicare (PDP)—Choice) OOP amounts were obtained from the *Medicare.gov* Part D Planfinder for an applicable beneficiary living in Washington DC (20201).

2. Absence of WAC as Potentially Misleading

Comment: Many commenters strongly opposed the use of the WAC and expressed concern that the WAC is not a meaningful measure of what a patient will pay for a drug and is instead misleading and confusing. Commenters noted that, based on insurance coverages, rebates, patient assistance programs, and negotiated discounts, consumers could pay less for a drug with a higher list price than for a drug with a lower list price and that disclosure of the WAC does not provide accurate or relevant information to patients. Commenters expressed concern that the proposal will deter patients from seeking appropriate care, as some may believe the WAC represents their out of pocket costs. Commenters noted their belief that the proposal puts the burden of increasing drug prices on consumers and stated that disclosing the price out of context will overemphasize costs. Commenters noted that the WAC is useful only if patients have a detailed understanding of the provisions of their drug coverage. Commenters stated that if information about OOP costs cannot be included, we should not require inclusion of any prices at all.

Response: We disagree that disclosure of a drug's WAC would be misleading. For the reasons stated above, WAC is a highly relevant data point with significance in both federal and commercial health care. Indeed, it is our view that the absence of a drug's WAC would make a DTC television advertisement potentially misleading because consumers appear to dramatically underestimate their OOP costs for expensive drugs, but once they learn the WAC they become far better able to approximate their OOP costs. In the 2019 JAMA study,[31] published after the proposed rule was issued, researchers asked subjects to estimate their monthly OOP costs for a drug with a hypothetical WAC of $15,500 per month. When subjects were provided no information about price, they responded that their OOP costs would be, on average, $78 per month or about 0.5 percent of the WAC. However, when subjects were told the WAC, they more accurately determined their (OOP) costs at $2,787 or about 18 percent of the WAC. We do not know whether subjects used their own plans as the bases for their calculations and if so, the report does not reveal their plans' coinsurance rates. Nonetheless, the informed estimates were far closer to what one would expect to see paid at the pharmacy counter under most plans than the uninformed assessment of $78. This study strongly suggests that advertisements without the WAC may lull viewers into a false sense affordability and may therefore be potentially misleading under the relevant state laws. *See, e.g.,* Calif. Bus. & Prof. Code sec. 17200.

We also disagree with commenters' concerns that the list price may be more confusing than beneficial to patients because it is not related to their OOP costs. As noted above, consumers may be better able to predict their OOP costs when they know a drug's WAC. In addition, the list price will be new information to patients, and a starting point for conversations among prescribers, patients and caregivers. We believe it would be too complicated to require manufacturers to try to disclose every possible cost sharing outcome in a DTC television advertisement, but requiring disclosure of the list price will help prompt further discussions that help consumers make informed decisions about appropriate treatment options. (As discussed elsewhere in this preamble, the rule also requires inclusion of the statement, ''If you have health insurance that covers drugs, your cost may be different,'' a further disclosure that provides context for consumers.) As noted above, the list price is relevant for uninsured patients, and insured patients with deductibles and coinsurance as is frequently the case under Part D for high cost drugs advertised on television.

We disagree that disclosure of a drug's WAC in DTC television advertisements will overemphasize costs or deter patients from seeking care. As noted in the 2019 JAMA Study, the risk of patients not seeking care is mitigated

[31] Garrett JB, Tayler WB, Bai G, *et al.* Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''2019 JAMA Study'').

when the advertisement includes a caveat that OOP costs may be less.[32]

Comment: Some comments cite evidence that the disclosure of the list price may dissuade patients from discussing certain medical treatments with their prescribing health care practitioners.[33] In support of the dissuasion argument, at least one comment also cited to an article about a study that concluded that high deductibles discourage patients from seeking prompt medical care.[34] Another comment disagreed, asserting that companies advertising their products expend considerable resources to ensure that their advertising communicates effectively. The comment further asserts that consumers who are able to understand and make use of the information about a prescription drug or biological product described in the advertisement would have the capacity to understand and make use of the pricing information.

Response: We find the latter comment more persuasive. The article from the New England Journal of Medicine was published under the ''Perspectives'' heading, which the journal describes as ''[c]over[ing] timely, relevant topics in health care and medicine in a brief, accessible style.'' *See https://www.nejm.org/author-center/article-types.* The authors opine that ''a *potential* unintended consequence of price disclosure *may be* to dissuade patients from seeking care because of the perception that they cannot afford treatment'' (emphasis added).[35] This statement of the authors' opinion is not based on any data, and we do not find it persuasive. We are also not persuaded that the study on high deductibles undermines the DTC ad requirement. That study concluded that individuals who transitioned from low-deductible to high-deductible insurance demonstrated a delay in seeking care for certain diabetes complications, as compared to peers who remained in low-deductible plans. Furthermore, the study suggests that people with diabetes should select benefit designs that are appropriately tailored to their expected use of care. But the proposition that individuals, if informed of a drug's list price, will necessarily delay visiting a doctor and discussing treatment options (including but not limited to the advertised drug) does not necessarily follow from the study's conclusion.

In contrast, as we discussed in section I.C., price transparency is essential to enable consumers to make informed health care choices, which will in turn improve the efficiency of the Medicare and Medicaid programs, as it is critical that beneficiaries understand the costs associated with various medications. This is especially important where consumers have significant cost sharing obligations. Increasing drug price transparency changes patient behavior, and price transparency is an accepted strategy for addressing our increasing health care costs. Additionally, price transparency is recognized as a low-risk intervention because it has the potential to reduce health care costs without otherwise affecting health care delivery and reimbursement.[36]

Comment: Many commenters note that including the list price could be a psychological burden for patients, whether or not it is related to their OOP costs, because many advertised drugs are expensive, sole source drugs for severe, debilitating, or terminal diseases. This means patients often will not have the opportunity to ''shop'' for lower cost alternatives. Some commenters note that patients should not be the one bearing the responsibility for making cost-benefit analyses when they are undergoing active treatment for severe disease, so it is inappropriate to include the list price as an element for patients to consider as they enter active treatment. Commenters also stated that including the list price could also have the unintended consequence of patients' electing to use higher-cost drugs, particularly if there is no difference in OOP costs, because price is seen as an indicator of quality in other categories of consumer goods.

Response: While we acknowledge that a person's clinical needs or health condition may make it infeasible for them to seek lower cost drug therapies, we disagree that this makes the provision of list price information inappropriate. We believe providing this information regarding price is better than providing no information, even if the additional information is not considered by a particular patient and his or her providers in making treatment decisions. Contrary to commenters' assertions, it may be more burdensome for patients and their caregivers not to have pricing information to take into consideration as they determine the most appropriate course of action. Moreover, we would not characterize any decision to prescribe a higher cost drug, based on consideration of all the applicable factors including safety, efficacy, side effects, and price, as an unintended consequence of this rule.

Comment: Commenters noted that because WAC has no relation to what patients will actually pay, it is unreasonable to assume the proposal will have any impact on treatment choices or the cost of drugs.

Response: We disagree. As discussed above, studies show that consumer behavior is affected by DTC advertisements, and that consumers who know the list price may be better able to predict their OOP costs. This evidence leads to the conclusion that the additional data point, which, as discussed elsewhere in this rule, is highly relevant and would have an effect on treatment choices and, potentially, the cost of drugs.

Comment: A few commenters expressed concern that disclosing the WAC fails to account for the value of drugs and could lead to consumers comparing drugs based on the WAC alone, without considering important factors such as safety and effectiveness.

Response: We disagree that providing this limited price information would lead to decision making that disregards safety and effectiveness. Given that the drugs and biological products that are subject to this rule are dispensed upon a prescription, and therefore require consultation with a prescriber, the choice of an appropriate treatment option is not based solely on a drug's WAC.

Comment: A few commenters expressed concern that the proposed disclosure of the WAC in DTC advertisements undermines FDA efforts to make advertisements simple and clear to patients.

Response: We disagree. The DTC disclosure requirement we are finalizing in this rule requires simple, standardized text be placed at the end of the ad, and would not make the advertisement any more complicated. However, we remind manufacturers that they have to comply with all applicable FDA requirements and that nothing in this rule is intended to supersede any FDA requirement.

Comment: Some commenters note that providers and prescribers do not

[32] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''2019 JAMA Study'').

[33] Dusetzina SB and Mello MM. Disclosing Prescription-Drug Prices in Advertisements—Legal and Public Health Issues. N Engl J Med. 2018 Dec 13;379(24):2290–2293.

[34] Gordon S. High Deductibles May Mean Poorer Diabetes Care. U.S. News & World Report, Nov. 20, 2018. *https://health.usnews.com/health-care/articles/2018-11-20/high-deductibles-may-mean-poorer-diabetes-care.*

[35] Dusetzina SB and Mello MM. Disclosing Prescription-Drug Prices in Advertisements—Legal and Public Health Issues. N Engl J Med. 2018 Dec 13;379(24):2290–2293.

[36] Sinaiko AD and Rosenthal MB. Increased price transparency in health care—challenges and potential effects. N N Engl J Med. 2011 Mar 10;364(10):891–4.

have the time, resources, or expertise to have conversations with patients about the cost of drugs or biological products, so it may be inappropriate to provide list price information to patients encouraging them to discuss this information with their providers or prescribers. Commenters stated that DTC television advertising may actually decrease the quality of conversations between patients and their providers because it will force the provider to dedicate a portion of their limited time with the patient discussing a list price unrelated to their OOP costs that the physicians are not trained to discuss. Some commenters note that the payor or the pharmacists may be better equipped to educate the patient on the cost of therapies.

Response: This rule does not require that providers and prescribers discuss pricing or costs with their patients. Rather, this rule merely requires that relevant information be shared with patients should providers and prescribers wish to discuss drug costs with them. We believe it is important that providers discuss any barriers to medication adherence, such as cost, with their patients to determine if consideration of alternative therapies is needed. The availability of list price information will not decrease the quality of doctor-patient interaction or require any particular training or resources. In fact, it may encourage patients to discuss any barriers to medication adherence with their providers. As discussed in section F of this final rule, certain Medicare billing codes already account for the resources associated with counseling patients on therapeutic options.

3. Use of a $35 Threshold

We sought comment as to whether the cost threshold of $35 to be exempt from compliance with this rule is the appropriate level and metric for such an exemption. We proposed this threshold because it approximates the average copayment for a preferred brand drug. We also considered incorporating a range for exempted drugs defined as less than $20 per month for a chronic condition or less than $50 for a course of treatment for an acute condition. In particular, we considered whether ''chronic condition'' and ''acute condition'' are sufficiently distinguishable to accomplish the stated regulatory purpose. We sought comment on alternative approaches to determining a cost threshold, whether or not the threshold should be updated periodically, and if so, how the threshold should be updated.

Comment: Some commenters agree that $35 is a reasonable cost threshold to be exempt from compliance with this rule. Many commenters recommend that we do not include a threshold price for drugs that would exempt them from including their list price in DTC advertising. They note that if one of the purposes of this rule is to improve price transparency, then it is important to provide the prices on all drugs and biological products that are subject to DTC advertising. Some of these commenters also note that it is not appropriate to assume that $35 is a good threshold as an approximation of the co-payment of an average copayment for a preferred brand drug because $35 may still be a financial burden for many patients, and awareness of this amount could be useful for patients. One commenter recommended that we reduce the threshold to $25 because that is also representative of copayments for brand drugs. Another commenter recommended that we increase the threshold to $100 to avoid inundating patients with price notifications, and potentially reducing their effect. Finally, several commenters noted that it may be confusing to patients on why some drugs and biologic products have a list price included in their DTC television advertisements, while others do not. To avoid this confusion, the price should be included in all advertisements. We did not receive any comments on whether or how often this threshold would need to be revisited.

Response: We agree with commenters that $35 is an appropriate list price threshold for exemption from compliance with this rule. We disagree with commenters that suggested there should not be an exemption from the list price disclosure requirement. Since patients with the traditional benefits with no low income cost subsidies can already expect to pay up to $35 in cost sharing for a preferred brand drug, knowing the list price of low-cost drugs is unlikely to affect their drug purchasing decisions. We appreciate commenters' recommendation to reduce the threshold to $25, but we continue to believe that $35 is a more appropriate threshold, given that it frequently is the copayment amount for preferred brand drugs. For the same reason, we decline to adopt the suggestion to raise the threshold to $100. Also, there are likely not many additional drugs that would receive the exemption if we move it from $35 to $100. Finally, we disagree that it will be confusing to patients that some drugs and biological products include prices in their DTC advertising while others do not because drugs and biological products that do not have the price displayed will be within the range of what they would expect to pay for a prescription regardless of insurance coverage or structure, or if they are uninsured. DTC advertisements that do not have prices will be just like advertisements on television today. Moreover, nothing in this rule prevents a manufacturer from including its WAC even though it is exempt. Advertisements with prices will simply provide additional information that can help beneficiaries engage their doctors and make appropriate treatment decisions.

D. First Amendment Considerations

1. Background—Zauderer/Central Hudson

As an initial matter, the speech here at issue does not implicate core First Amendment interests. Manufacturers already disclose the very same information at issue, their products' WACs, to purchasers as well as publishers of various pricing databases and other compendia. As the Supreme Court has explained, ''Our lodestars in deciding what level of scrutiny to apply to a compelled statement must be the nature of the speech taken as a whole and the effect of the compelled statement thereon.'' *Riley* v. *Nat'l Fed'n of Blind,* 487 U.S. 781, 796 (1988). The key concern relating to compelled speech is having the government compel a speaker to convey a message with which it disagrees. *Johanns* v. *Livestock Mktg. Ass'n,* 544 U.S. 550, 557 (2005); *see, e.g., Nat'l Inst. of Family and Life Advocates* v. *Becerra,* 138 S. Ct. 2361, 2379 (2018) (''*NIFLA*'') (law at issue ''compel[ed] individuals to contradict their most deeply held beliefs, beliefs grounded in basic philosophical, ethical, or religious precepts'') (Kennedy, J., concurring). More routine disclosure requirements are ''simply not the same as forcing a student to pledge allegiance[ ] or forcing a Jehovah's Witness to display the motto 'Live Free or Die.' '' *Rumsfeld* v. *Forum for Academic & Institutional Rights, Inc.,* 547 U.S. 47, 62 (2006). The ''disclos[ure of] objective facts and statistics'' about price information ''is simply not the same as forcing a speaker to support or accommodate an idea, belief, or opinion.'' *Beeman* v. *Anthem Prescription Management, LLC (''Beeman''),* 315 P.3d 71, 84 (Cal. 2013) (citations and internal punctuation omitted).

It is therefore well established that the government may, consistent with the First Amendment, require the disclosure of factual information in marketing

commercial products where the disclosure is justified by a government interest and does not unduly burden protected speech. *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626 (1985); *NIFLA,* 138 S. Ct. at 2372. The rule's required disclosure meets this test. The list price is a fact that is controlled by the manufacturer; it does not represent a government viewpoint or policy message. Price transparency enhances the information available in the market and allows markets to function more efficiently to the benefit of consumers. And the brief textual statement placed at the end of a television advertisement would not unduly burden the advertiser's ability to convey its message in the remainder of the advertisement.

Many comments assert that the rule should be evaluated under the intermediate scrutiny test for commercial speech articulated in *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557 (1980). Under that test, agencies can regulate speech where the regulation advances a substantial government interest and the regulation is no more extensive than necessary to serve that interest.

Although we believe that *Zauderer* provides the appropriate framework for review, the rule also satisfies the elements of the *Central Hudson* test. The government interest is clear. Prescription drug spending in the United States has increased dramatically in recent years and is projected to account for an increasing share of the country's health care spending. This affects consumers both through their own OOP expenses and through the expenses borne by Medicare and Medicaid and taxpayers. Price transparency helps improve market efficiencies by helping consumers make informed choices and the disclosure of price information clearly and directly advances this interest. The brief disclosure at the end of a prescription drug advertisement is narrowly tailored to achieve that result and does so more effectively than alternatives that do not provide the information in the advertisement itself.

2. Application of the Zauderer Test

Comment: Some comments assert that the *Zauderer* test applies only where the government interest relates to preventing consumer deception. In contrast, at least one comment noted that some lower court cases have recognized other interests. Another comment stated that the United States Supreme Court has not resolved the issue.

Response: The latter comments more accurately summarize the current state of the law. While some lower court decisions could be read to limit the application of *Zauderer* to matters where the government interest relates to preventing consumer deception, *e.g., Entm't Software Ass'n* v. *Blagojevich,* 469 F.3d 641, 651–53 (7th Cir. 2006), other courts have held that *Zauderer* applies where other interests support the compelled speech. *See, e.g., Am. Bev. Ass'n* v. *City & Cty. of San Francisco,* 916 F.3d 749, 755–56 (9th Cir. 2019) *(en banc); Am. Meat Inst.* v. *United States Dep't of Agric.,* 760 F.3d 18 (D.C. Cir. 2014) (en banc). The Supreme Court did not reach this issue in *NIFLA. See* 138 S. Ct. at 2377. It is our view, based on current law, that the *Zauderer* test is not limited to disclosures designed to prevent consumer deception.

Comment: Several comments assert that the *Zauderer* test applies only to mandated disclosure of ''purely factual and uncontroversial'' information, but that the WAC, even if a literally true, should not be considered factual and uncontroversial because many patients would pay less, and therefore the WAC is incomplete, misleading, and will be misunderstood. Other comments argued that the disclosed prices ''for a typical 30-day regimen or for a typical course of treatment'' will often be inaccurate for certain drugs, where the course of treatment varies based on patient-specific factors such as age, weight, or baseline test results. Some comments further assert that by misleading patients, the compelled disclosure of inflated prices could dissuade patients from seeking appropriate treatment.

Response: We disagree with these comments. The rule requires the disclosure of ''the current list price for a typical 30-day regimen or for a typical course of treatment.'' The current list price for a prescription drug or biological product is an objective fact. As discussed above, the WAC is a manufacturer-specified metric that is commonly used, reported in compendia, defined in statute, and relevant to both federal and commercial health care programs.

As discussed in the proposed rule, price disclosure requirements are commonplace under federal, state, and local laws, and have been upheld when challenged under the First Amendment as permissible disclosures of factual and uncontroversial information. *See, e.g., Spirit Airlines, Inc.* v. *United States Dep't of Transp.,* 687 F.3d 403, 414 (D.C. Cir. 2012); *Poughkeepsie Supermarket Corp.* v. *Dutchess Cnty,* 648 Fed. Appx. 156, 157–158, 2016 U.S. App. LEXIS 8770 (2d Cir. 2016)*; see also Beeman,* 58 Cal. 4th at 341, 315 P.3d at 78, 165 Cal. Rptr. 3d at 809 (upholding compelled disclosure of pharmacy fees under the right to free speech guaranteed by article I of the California Constitution, which is ''at least as broad as and in some ways is broader than the comparable provision of the federal Constitution's First Amendment'') (citations and internal punctuation omitted). The ''disclos[ure of] objective facts and statistics'' about price information ''is simply not the same as forcing a speaker to support or accommodate an idea, belief, or opinion.'' *Beeman,* 58 Cal. 4th at 349, 315 P.3d at 84, 165 Cal. Rptr. 3d at 816 (citations and internal punctuation omitted). And as the Supreme Court confirmed in *NIFLA,* ''we do not question the legality of . . . purely factual and uncontroversial disclosures about commercial products.'' 138 S. Ct. at 2376.

The rule further requires the disclosure to contain the following statement: ''If you have health insurance that covers drugs, your cost may be different.'' Again, this is undeniably a truthful statement of objective fact. Moreover, it directly addresses the issue raised in some of the comments in that it contextualizes the list price information. The assertions in the comments that consumers will misunderstand the price disclosure with this additional context are purely speculative. In addition, nothing in the rule would prevent the manufacturer from presenting additional contextual information, should the manufacturer wish to do so. However, we remind manufacturers that they have to comply with all applicable FDA requirements and that nothing in this rule is intended to supersede any FDA requirement.

Comment: At least one comment asserts that disclosure of the WAC is controversial because pharmaceutical pricing is a controversial topic, and therefore even if the *Zauderer* test for permissible compelled disclosures did apply, it would not be satisfied here. The comment cites *NIFLA* and *Nat'l Ass'n of Mfrs.* v. *SEC,* 800 F.3d 518 (D.C. Cir. 2015) as support for this proposition.

Response: We disagree with this comment and the applicability of the cited cases. First, because the WAC is a truthful statement of objective fact that is not subject to dispute, it is ''uncontroversial.'' Indeed, all drug manufacturers provide this information voluntarily to companies who publish this information in compendia or databases available to the public, and we note that one drug manufacturer

voluntarily chose to include the list price of their more commonly prescribed drug prior to the establishment of a legal requirement to do so. Second, under the case law, it is not clear that ''uncontroversial'' or ''noncontroversial'' is a legal standard that is part of the *Zauderer* test. *See Disc. Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 559 n.8 (6th Cir. 2012) (The test under *Zauderer* is ''factual'' and ''accurate''; the Court in *Zauderer* used the term ''noncontroversial'' once to ''merely describe[ ] the disclosure the Court faced in that specific instance.''). Indeed, some cases have not mentioned ''uncontroversial'' or ''noncontroversial'' in the course of applying the *Zauderer* test. *See, e.g., Milavetz, Gallop & Milavetz, P.A.* v. *United States,* 559 U.S. 229 (2010); *Spirit Airlines, Inc.,* 687 F.3d 403.

In *NIFLA,* the Supreme Court held that the *Zauderer* test applies only to required disclosures about the speaker's own product or service, and therefore it did not apply to a disclosure about the availability of state-sponsored medical services (including, in that case, the potential provision of abortion services). *See* 138 S. Ct. at 2372. Although the Court noted that abortion is ''anything but an 'uncontroversial' topic,'' that statement does not appear to be the basis for its finding that *Zauderer* did not apply to the disclosure about state-sponsored services. *See id.* Here, by contrast, the disclosure required by the rule relates to the product being advertised, thus falling squarely within the traditional ambit of the *Zauderer* test.

Unlike the 6th Circuit holding in *Discount Tobacco,* the D.C. Circuit held in *Nat'l Ass'n of Mfrs* that ''uncontroversial'' is part of the *Zauderer* test. However, the holding in that case underscores that a drug's list price is not ''controversial.'' At issue in that case was a requirement that companies report to the SEC and state on their website if any of their products ''have not been found to be DRC conflict free''—which the court described as ''a metaphor that conveys moral responsibility for the Congo war'' and ''compel[s] [a company] to confess blood on its hands.'' 800 F.3d at 530. A disclosure of the list price of a prescription drug or biological product is hardly comparable, and courts have upheld required disclosures similar to the one here. *See, e.g., Spirit Airlines, Inc.,* 687 F.3d 403 (upholding requirement for airlines to make total price the most prominent cost figure in advertisements); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 134 (2d Cir. 2009) (upholding required posting of calories on menus in chain restaurants); *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell, 272 F.3d 104* (2d Cir. 2001) (upholding requirement that mercury-containing products be labeled with a statement that the products contain mercury and, on disposal, should be recycled or disposed of as hazardous waste). Thus, even if ''uncontroversial'' is part of the *Zauderer* test and given the meaning adopted by the court in *Nat'l Ass'n of Mfrs,* the disclosure of price information is uncontroversial.

Comment: Some comments assert that the required disclosures are not adequately justified. Some state that the government goal of encouraging the selection of cost-effective therapies cannot justify the compelled disclosure of the WAC, because the WAC is not the kind of health care economic information that would facilitate informed price-shopping and providing pricing in advertisements is too disconnected from purchasing decisions, which are often made during physician-patient discussions. Other commenters claimed that CMS assumed, without sufficient evidence, that higher drug costs result from a lack of transparency about drug prices, and that CMS failed to explain why the disclosure of the WAC would be effective in light of the distortions in the market created by third-party payors. Commenters also stated the rule would fail to advance the government's interests because it would simply result in manufacturers shifting advertisements from TV to other forms, such as online or through social media. One comment asserts that the required disclosure is unnecessary because many prescription drug manufacturers will begin voluntarily providing this pricing information on their websites pursuant to a document issued by the Pharmaceutical Researchers and Manufacturers of American (''PhRMA''), entitled *PhRMA Guiding Principles-Direct to Consumer Advertisements About Prescription Medicines.* That document was revised in October 2018 to include a new price disclosure principle recommending that prescription drug broadcast advertisements include direction to where patients can find information about the cost of the medicine, such as a company-developed website.

Response: We disagree with these comments—the rule is more than adequately justified. The *Zauderer* test requires that compelled disclosures ''remedy a harm that is potentially real [and] not purely hypothetical.'' *NIFLA,* 138 S. Ct. at 2377 (citation and internal punctuation omitted). Here, the harm is clearly real. As discussed in section I.C. above, rising drug prices increase federal health care costs, threatening the sustainability of federal health care programs and the availability to care to Medicare and Medicaid beneficiaries, and are a harm to beneficiaries by increasing their health care and OOP costs.

PhRMA's issuance of a new guiding principle in October 2018 does not change the need for the rule. The PhRMA principles are voluntary; they are not binding on PhRMA members, let alone non-members, and there is nothing to prevent PhRMA from revising its principles at any time, a fact which is underscored by the timing of the issuance of the guideline to coincide with the issuance of the proposed rule. Moreover, including direction to where price information can be found will not have the same impact as including the information in the advertisement itself. As noted in section II.E.7. of this rule, one third of adults surveyed stated that they do not frequently use the internet, making the PhRMA proposal relatively meaningless to that cohort. As to the other two thirds who do, the PhRMA proposal would require them to immediately open their browser, navigate to the URL flashed on the television screen, and then click through to find the pricing information. We believe that relatively few viewers will make use of the approach advocated by the PhRMA proposal, even assuming that its members implement the proposal.

Comment: Some comments assert that the rule would be unduly burdensome in that it would clutter the advertisement and would require monthly updates.

Response: We disagree. ''[C]ompliance with most compelled disclosure laws will logically entail some expense.'' *Poughkeepsie Supermarket Corp.* v. *Cnty. of Dutchess,* 140 F. Supp. 3d 309, 317 (S.D.N.Y. 2015), aff'd 648 Fed. Appx. 156, 157–158, 2016 U.S. App. LEXIS 8770 (2d Cir. 2016). Courts, however, have not found them to be unduly burdensome unless they ''drown[ ] out the [speaker's] own message'' or ''effectively rule[ ] out'' a mode of communication. *NIFLA,* 138 S. Ct. at 2378. As we explained in the proposed rule, the requirement to add certain information to an advertisement is not unduly burdensome where, as here, the manufacturer has the ability to convey other information of its choosing in the remainder of the advertisement. *See, e.g., Spirit Airlines, Inc.,* 687 F.3d at 414 (requirement for airlines to make total price the most prominent cost figure does not significantly burdens

airlines' ability to advertise); *Discount Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 524 (6th Cir. 2012) (size of required warnings is not unduly burdensome where remaining portions of their packaging are available for other information). The inclusion of a brief textual statement at the end of a broadcast advertisement neither drowns out the speaker's message nor rules out broadcast advertisements as a mode of communication.

Even if economic burden were relevant under *Zauderer,* the burden here is minimal. First, most manufacturers report the WAC to compendia and databases for other business purposes. Second, we are narrowly limiting the amount of information included on the advertisements and the advertisements subject to this policy to minimize the burden on manufacturers and advertising platforms to only deliver the minimum amount of necessary information to implement the policy. Finally, the fact that one pharmaceutical manufacturer is voluntarily including list prices in its television advertisements shows that including these prices is a minimal burden to the manufacturers.[37] Finally, the Regulatory Impact Analysis in section IV shows that the cost to implement this change would cost less than 0.1 percent of what manufacturers spend on DTC television advertising.

Comment: Some comments assert that the rule will be burdensome on other actors in the chain of distribution such as broadcasters and cable operators, particularly in that the disclosure requirement will have the effect of diverting the advertising revenue to different media.

Response: Spending on DTC pharmaceutical commercials increased 62 percent between 2012 and 2017.[38] Studies estimate that every dollar spent on DTC advertising increases sales on the advertised drug by $2.20–$4.20.[39] Because of the value and return on investment related to DTC advertising,[40] it is unlikely that adding the list price of pharmaceuticals to DTC television advertising will significantly affect the amount spent by that sector on television advertisements (*i.e.,* $4.2 billion in 2017).

In addition, we disagree that this type of alleged impact is properly part of the First Amendment analysis. The undue burden that the *Zauderer* test contemplates is an undue burden on ''protected speech,'' not the economic impact on other actors. *See NIFLA,* 138 S. Ct. at 2377.

Comment: Some comments assert that government-scripted speech is always burdensome.

Response: We disagree. There are many products and services regulated under federal, state, and local laws for which disclosures are required. *See Reed* v. *Town of Gilbert,* 135 S. Ct. 2218, 2234–35 (2015) (Breyer, J., concurring); *Beeman,* 58 Cal. 4th at 366–67, 315 P.3d at 96–97, 165 Cal. Rptr. 3d at 830–31. And the Court in *NIFLA* confirmed that ''we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.'' 138 S. Ct. at 2376. Thus, the fact that many of these disclosures are ''government-scripted'' does not make them unconstitutional.

Moreover, disclosure of price information is fundamentally different from the viewpoint discrimination that lies at the heart of First Amendment protections. ''Required disclosure of accurate, factual commercial information presents little risk that the state is forcing speakers to adopt disagreeable state-sanctioned positions, suppressing dissent, confounding the speaker's attempts to participate in self-governance, or interfering with an individual's right to define and express his or her own personality.'' *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 114 (2d Cir. 2001).

The disclosure required by the rule is:

The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.

The bracketed language will be drafted by the company and the list price will be incorporated by the company. The few remaining words that constitute ''scripted'' language do not unduly burden First Amendment values.

Accordingly, we conclude that this final rule is constitutionally proper under the *Zauderer* test.

3. Application of the *Central Hudson* Test

Comment: Most comments did not dispute that the government interests described in the preamble to the proposed rule are substantial. Some comments affirmatively assert that HHS has a substantial interest in reducing Medicare and Medicaid costs. One comment, however, asserts that the proposed rule failed to establish that HHS's interest in the efficient administration of both Medicare and Medicaid programs was substantial.

Response: We agree with the comments that affirm the substantial government interest in reducing prescription drug or biological product costs generally, as well as the costs borne by Medicare and Medicaid. As discussed in section I.C.2.a. above, DTC advertising increases both utilization and costs of pharmaceuticals. Because DTC advertising has a direct impact on the utilization of prescription drugs or biological products, and the drugs most frequently advertised on television are high-cost drugs, the link between DTC advertising and efficient administration of the Medicare and Medicaid program is clear. In our view, there is no question that this interest is substantial.

Comment: Some comments assert that the rule will not advance any substantial government interests. Some of these comments assert that disclosure of the list price to consumers would not be helpful to consumers because of the disparity between the list price and the price actually paid by most patients.

Response: We disagree. As discussed in section I.C.1., there is a substantial government interested in reducing list prices because list price is directly linked to a number of factors that directly tie to how much Medicare Part D patients will pay for their drugs. Increased spending on high-cost drugs harms CMS programs and CMS beneficiaries. Additionally, as discussed in Section II.C., the WAC is a good price metric to use to represent list price.

Comment: Some comments assert that disclosure of the list price will not reduce drug prices. Other comments assert that the record is not sufficient to support the conclusion that the rule will be effective and that further study is necessary. At least one comment asserts that the rule will directly advance the government interest in reducing the high cost of prescription drugs or biological products including reducing Medicare and Medicaid costs.

Response: We agree with the latter comment. As discussed in section I.C., it is well accepted that price transparency helps improve market

[37] Johnson and Johnson. What Cost Information Helps Patients in a TV Ad? We Asked Them. *https://www.jnj.com/our-company/what-cost-information-helps-patients-most-we-asked-them.*

[38] Kantar Media. Pharma ups the ante on DTC advertising. *https://www.kantarmedia.com/us/newsroom/km-inthenews/pharma-ups-the-ante-on-dtc-advertising.*

[39] Ventola CL. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? P T. 2011 Oct; 36(10): 669–674, 681–684.

[40] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''2019 JAMA Study'')

efficiencies by helping consumers make informed choices. Disclosure of price information clearly and directly advances this interest. *Cf. Spirit Airlines, Inc.,* 687 F.3d at 415. Including the price of pharmaceuticals in DTC consumer advertising does change patient behavior, as discussed in section I.C. above. At the same time, any potential risks of being a barrier to access can be mitigated by notifying patients that the price may not reflect what the patient will pay OOP. Instead, it will create an opportunity for conversation between the patient and provider.[41]

Comment: At least one comment asserts that the rule could cause companies to withdraw their television advertisements in favor of other media.

Response: We find this scenario highly unlikely. As discussed, above, the heath care and pharmaceutical industry spent over $4.2 billion on DTC advertising in 2017,[42] up to a 4 fold increase in spending on the advertised drug for every dollar spent on DTC.[43] Given the popularity of TV among potential purchasers of a manufacturer's drugs as discussed in Section II.A, we have no basis to conclude that manufacturers would stop advertising on TV in favor of other media.

Comment: Some comments assert that the rule is not appropriately tailored to advance the government interests. At least one comment asserts that it is underinclusive in that the media is limited to television advertisements and drug products are limited to those reimbursed by Medicare and Medicaid. The comment also opined that rule is overinclusive in that it would cover drugs for which there is no alternative.

Response: We disagree with these comments. The *Central Hudso*n standard does not require the government to employ ''the least restrictive means'' of regulation or to achieve a perfect fit between means and ends. *Lorillard Tobacco Co.* v. *Reilly,* 533 U.S. 525, 556 (2001). Instead, it is sufficient that the government achieve a ''reasonable'' fit by adopting regulations ''in proportion to the interest served.'' *Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989) (citation omitted). As long as the regulation is ''[w]ithin those bounds'' of reasonable fit and proportion, the agency may determine ''what manner of regulation may best be employed.'' *Id.* The final rule starts with television advertising because we want to define the rule as narrowly as possible to achieve the goal improving price transparency and reducing the costs of prescription drugs and biological products. Since DTC television advertising makes up the majority of DTC spending, this is a good place to start to have the largest impact with the smallest burden. We reserve the right to expand the rule to include other media formats through future rulemaking.

As discussed above, the rule targets television advertisements for drugs because television advertising makes up the largest portion of DTC spend and has an outsized impact compared to other forms. As we try to educate as many patients as possible with this valuable information, as manufacturers do with their advertisements, we want to focus on the most commonly used and broadest reaching medium. This will allow us to maximize the number of patients educated while minimizing burden on manufacturers. The scope is limited to Medicare and Medicaid because we can directly link the lack of information and transparency on drug pricing to harm to those programs and their beneficiaries.

We disagree with the concern that providing the price for drugs or biological products that have no alternatives is overinclusive. As discussed above, the purpose of this rule is to provide valuable information about the drugs and biological products to the patient facilitate conversations and shared decision-making with their providers. The purpose is not to deter patients from using high cost prescription drugs and biological products. In the case of drugs and biologic products that have no alternative, the price will still be an informative talking point.

Comment: Some comments assert that the preamble to the proposed rule incorrectly cited *Red Lion Broad. Co.* v. *FCC,* 395 U.S. 367, 390 (1969) because the ''fairness doctrine'' at issue in that case is inapplicable here.

Response: We agree that the fairness doctrine is inapplicable to this rule. The preamble to the proposed rule cited *Red Lion Broadcasting* for the much more limited proposition that the Supreme Court has recognized that broadcast advertisements can be a particularly powerful means for conveying information to listeners.

Comment: Some comments assert that there are better alternatives that would be less burdensome on speech. Some comments assert that HHS should encourage companies to institute voluntary price disclosure measures, which the comments assert are preferable to compelled speech. At least one comment disagrees and asserts that, since corporations owe duties to their shareholders, not to the public, they should not be allowed to self-regulate.

Response: Since the issuance of the proposed rule, some manufacturers have made more pricing information, including list price, available on websites, and one manufacturer has begun to disclose list price information in some of its television advertisements. While we applaud these measures, we have concluded that voluntary measures will be insufficient to ensure the continued commitment of all of the relevant companies. We address the issue of manufacturer websites further below in section II.E.7.

4. Heightened and Strict Scrutiny

Comment: Some comments suggest that content-based compelled speech and speaker-based regulation should be subject to strict scrutiny or at least heightened scrutiny, citing *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218, 2226 (2015), *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552 (2011), and *NIFLA.*

Response: We disagree with these comments. As discussed above, HHS believes that this rule is properly reviewed under *Zauderer.* In *Reed* v. *Town of Gilbert,* the Court applied strict scrutiny to content-based restrictions on non-commercial speech in public fora. In that opinion, the Court stated that, ''[c]ontent-based laws—those that target speech based on its communicative content—are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.'' 135 S. Ct. at 2226. However, as Justice Breyer explained in his concurring opinion, many regulatory programs ''inevitably involve content discrimination''; applying strict scrutiny to those programs would ''write a recipe for judicial management of ordinary government regulatory activity.'' *Id.* at 2234–35 (Breyer, J., concurring). Lower courts have subsequently held that *Town of Gilbert* does not apply to the regulation of commercial speech. *See, e.g., Sarver* v. *Chartier,* 813 F.3d 891, 903 n.5 (9th Cir. 2016). And the Supreme Court has not applied strict scrutiny to the content-based regulations in decisions issued after *Town of Gilbert,* namely *Matal* v. *Tam,* 137 S. Ct. 1744 (2017), *Expressions Hair Design* v. *Schneiderman,* 137 S. Ct. 1144, 1151 (2017), and *NIFLA* itself.

[41] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''2019 JAMA Study'')

[42] Kantar Media. Pharma ups the ante on DTC advertising. *https://www.kantarmedia.com/us/newsroom/km-inthenews/pharma-ups-the-ante-on-dtc-advertising.*

[43] Ventola CL. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? P T. 2011 Oct; 36(10): 669–674, 681–684.

The Supreme Court in *Sorrell* suggests that content- and speaker-based restrictions would be subject to ''heightened scrutiny,'' but nevertheless continued to apply the ''commercial speech inquiry'' as outlined in *Central Hudson. Sorrell* v. *IMS Health Inc.,* 564 U.S. 552, 571–72 (2011). That led to debate in the lower courts about whether heightened scrutiny is a different standard from *Central Hudson* and, if so, what the test is and when it is applied. *See, e.g. Retail Digital Network, LLC* v. *Prieto,* 861 F.3d 839 (9th Cir. 2017) (en banc) (''*Sorrell* did not mark a fundamental departure from *Central Hudson's* four-factor test, and *Central Hudson* continues to apply.''); *Wollschlaeger* v. *Florida,* 848 F.3d 1293 (11th Cir. 2017) (en banc) (applying ''heightened scrutiny'' to a content-based restrictions); *1–800–411-Pain Referral Service, LLC* v. *Otto,* 744 F.3d 1045, 1055 (8th Cir. 2014) (Because *Sorrell* did not define heightened scrutiny, *Central Hudson* applies to restrictions on commercial speech that are content- or speaker-based). Thus, the legacy of *Sorrell* remains unclear.

In addition, there have been suggestions that heightened scrutiny should be connected to viewpoint discrimination, and not more broadly to content-based regulation. *See Sorrell,* 564 U.S. at 565 (law under review ''goes even beyond mere content discrimination, to actual viewpoint discrimination''); *Matal,* 137 S. Ct. at 1767 (Kennedy, J., concurring) (''the viewpoint based discrimination at issue here necessarily invokes heightened scrutiny''). This distinction may be particularly important given that many regulatory programs necessarily involve both content- and speaker-based restrictions. *See Sorrell,* 564 U.S. at 589 (Breyer, J., dissenting) (''Regulatory programs necessarily draw distinctions on the basis of content. . . . Nor, in the context of a regulatory program, is it unusual for particular rules to be 'speaker-based,' affecting only a class of entities, namely, the regulated firms.'').

While the First Amendment jurisprudence continues to evolve, one thing is clear—the disclosure required by this rule does not implicate the concerns underlying *Sorrell* and many other cases—that is, the government's ''regulation of speech because of disagreement with the message it conveys.'' *Sorrell,* 564 U.S. at 566. Here, the rule requires merely the disclosure of price information regarding prescription drugs or biological products in television advertisements—objective, factual information that will help inform consumers and improve market efficiencies.

E. Requirements in DTC Advertising Other Than WAC

1. Medium To Include List Price

We sought comment on whether we should apply the proposed regulation to other media formats and, if so, what the presentation requirements should be.

Comment: Some commenters recommended that list price be included on all DTC advertising, such as radio, magazine, and online communication. Some commenters asked CMS to explain why this rule only applies to DTC advertisements on television. Including the prices on all media formats would support the goal of this rule in increasing transparency and informing patients. Several commenters recommend providing the list price to the patient and provider at the time of prescribing, which would require expanding beyond just television advertising, because this is when the provider and patient would best be able to use the information when making care decisions.

Response: We appreciate recommendations to include the list price on all forms of DTC advertising. We intend to only apply this rule to television advertising because we want to apply this rule as narrowly as possible to achieve our goal of promoting price transparency and reducing drug costs, with minimal burden on those providing the information. We appreciate commenters' recommendations to make the list price available at the time of prescribing. In our recent proposed rule titled ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' 83 FR 62152 (November 30, 2018), we proposed to require Part D sponsors to implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's e-prescribing and electronic medical system to provide complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit information, including cost, formulary alternatives, and utilization management requirements.

2. Typical Regimen—30 Days or Course of Treatment

We sought comment on whether 30-day supply and typical course of treatment are appropriate metrics for a consumer to gauge the cost of the drug.

Comment: Many commenters agreed that 30 days is an appropriate quantity for the purposes of providing a usable list price in a television ad, especially for chronic medications. One commenter suggested providing the cost for a 90-day supply because many payors prefer that patients fill their prescriptions for a 90-day supply. Some comments, including those that support using a 30-day supply, recommend including the annual cost instead of, or in addition to, the cost for 30-day supply.

Many commenters also agreed that the price for a typical course of treatment would be appropriate for drugs that are not taken chronically or do not have standard 30-day supply. Commenters note that it is important for CMS to provide specific guidance on the definition of a typical course of treatment, as this could be an opportunity for gaming to provide the cost for the minimum possible treatment.

Some commenters note that it is difficult for manufacturers to calculate a WAC or list price for a 30-day supply or a typical course of treatment because doses can vary dramatically for individual patients based on characteristics such as weight, gender, pharmacogenomics, renal and liver function, or severity of disease.

Response: We appreciate commenters' feedback. We are finalizing the requirement as proposed. While we understand that including the WAC for a 90-day supply or the annual cost may be useful for some patients, we believe that our requirement to include the WAC of a 30-day supply will provide sufficient information for patients to assess their costs on a monthly, or even a 90-day or other basis without being burdensome to manufacturers. In addition, we understand that payors generally cover chronic medication in monthly increments, which makes the 30-day price most relevant. In response to comments seeking further guidance on what constitutes a typical course of treatment, we decline to impose specific requirements for determining the typical course of treatment at this time. The manufacturers will be in the best position to determine what a typical course of treatment would be for their drugs, and therefore will be in the best position to determine the appropriate list price for a typical course of treatment, consistent with the disclosure requirement set forth at § 403.1202. We will monitor compliance and take appropriate action if warranted.

3. Other Information

We also sought comment on the content of the proposed pricing information statement as described herein, including whether other specifications should be incorporated.

Comment: Some commenters agreed with the general disclosure, ''If you have health insurance that covers your drug, your cost may be different'' because, while it does not provide the specifics of how different the OOP cost may be from the list price, it provides enough information for the patient to expect a different price based on his or her insurance. Other commenters believe that this is not enough of a stipulation, and that patients need additional context for the information to be meaningful.

Response: We appreciate commenters' support for the general disclosure about OOP costs. Although a general statement might not provide detailed information about each patient's OOP cost or address the potential confusion between list price and OOP cost for a patient, we believe it is sufficient because, as noted in section II.C.2., DTC advertising is a source of information for patients from which to start a conversation patient and provider or payor. This rule encourages such conversations by promoting price transparency without unduly burdening manufacturers. We therefore decline to require a more specific disclosure about a patient's OOP costs.

Comment: A few commenters recommended that CMS not expand the proposed disclaimer in such a way as to allow manufacturers to state the price of a drug after the consideration of a coupon or discount. Commenters noted that this would allow manufacturers to mask the true cost of their drugs.

Response: We are finalizing the standard disclaimer as proposed. We also note that this rule requires the inclusion in DTC television advertisements of the drug's WAC, which we have defined—consistent with section 1847A of the Social Security Act—to exclude prompt pay or other discounts. Thus, the pricing information that must be disclosed will not be obscured by the application of coupons or discounts.

4. Combination of Drugs

We sought comment on how to treat an advertised drug that must be used in combination with another non-advertised drug or device.

Comment: A few commenters recommended that, in the cases of drugs that are typically used in combination with other drugs, DTC television advertisements include a standardized statement, such as ''Note: this drug may require use in combination with another drug or device, whose price is not reflected in this cost.'' These commenters also recommended against trying to estimate or include costs associated with the other drugs that are typically included in combination.

Response: We appreciate commenters' recommendations to include a standardized statement alerting patients to the fact that this drug is often used in combination with other drugs. Although we decline to require inclusion of such a statement at this time, we encourage manufacturers of drugs typically used in combination with other drugs to include such a statement in their DTC television advertisements. We similarly decline to require that such a statement, if included in a DTC television advertisements, estimate or reflect costs associated with the other drugs, as we agree that may be confusing for patients.

5. Placement of Information/Content of the Statement (Including Use of Competitors' Prices)

We sought comment on whether the final rule should include more specific requirements with respect to the textual statement, such as specific text size, contrast requirements, and/or duration and specifically what those requirements should be.

Comment: Many commenters recommend that the information is displayed clearly in a way that is easy to see and easy for the average reader to read. Some commenters recommend that CMS specify requirements on font, size, location, and duration because without a clear, readable, and understandable standard format, manufacturers may intentionally make the information difficult to read or understand. Commenters also recommend reading the list price as part of the audio in addition to printing the price on the ad to further make the information available.

Other commenters recommended against specific requirements on how to display the list price in the ad because advertisements are extremely limited in time and space and recommended flexibility in order to develop an understanding of the best way to display this information. These commenters recommend that manufacturers be able to test different methods and details for displaying the information to best educate patients.

Response: We appreciate these comments. We will finalize § 403.1203 as proposed because we believe it provides a sufficiently detailed standard for how the information must be conveyed in the advertisement, while still allowing manufacturers flexibility to develop a format that—consistent with the regulatory standard—best conveys the required information. We will monitor compliance with the regulation and provide guidance as necessary. We also will consider adopting more detailed requirements through future rulemaking if warranted.

Comment: Two commenters recommended against allowing manufacturers to include an up-to-date competitor product's list price because they believe that manufacturers will always list the highest competitor price available, which may confuse patients if other cheaper alternatives are available. Other commenters support the option to provide the list price of a therapeutic competitor, because the list price is not useful to the patient without additional context.

Response: We appreciate these comments. Although we recognize commenters' concerns about gaming, we are finalizing this provision as proposed. Allowing manufacturers to provide an up-to-date competitor product's price, so long as they do it in a truthful and non-misleading way, will provide additional information that the patient can use to manage his or her care. We believe that providing information about the prices of therapeutic alternatives provides valuable context for the patient. However, we remind manufacturers that they have to comply with all applicable FDA requirements and that nothing in this rule is intended to supersede any FDA requirement.

6. Effective Dates of Price

We proposed to require that the list price be current as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. We sought comment as to whether a statement expressing an expiration date of the current price reflected in the advertisement should be incorporated into the required disclosure language so that consumers are informed that drug prices are subject to frequent changes and a drug price may differ from the date the advertisement is broadcast to the date that the drug is dispensed.

Comment: Many commenters recommended that DTC advertisements include a list price's expiration date to ensure that patients are acting on accurate information and to prevent manufacturers from intentionally providing misleading information. Commenters noted that, due to the frequency of prices changes, advertisements should specify the dates that the price is valid or when the price is expected to expire or change. Some commenters recommended specifying how timely the manufacturer must be in updating prices in the advertisements. A few commenters recommended that

CMS require that the price always be up-to-date when they appear in the advertisement. Finally, one commenter suggested that as an alternative to updating list prices, the advertisement could include the WAC over some look-back period to approximate what the current price may be.

Response: We appreciate these comments and are finalizing § 403.1202 as proposed, with minor technical modifications described below, meaning that the list price must be current, as determined on the first day of the quarter during which the advertisement is being aired or broadcast. As we anticipate that manufacturers update their WACs twice per year, we do not believe advertisements will need to be changed with significant frequency. We decline to require inclusion of a price's expiration date in the advertisement because we want to minimize the burden on manufacturers and because we do not think that the information would helpful to patients beyond what is already required. However, a manufacturer may specify the effective dates of its prices, should it choose, so long as the price listed is current (as determined under § 403.1202). As noted above, we are making technical changes to the regulation text at § 403.1202 to refer consistently to a typical course of treatment and to remove the quotation marks that do not pertain to the required text.

7. Use of Manufacturer Websites

Comment: Commenters suggested that in lieu of requiring the WAC in the advertisement, the government could require that advertisements include a reference to where price information can be found, such as a company website that would include the list price and other context about the potential cost of the medicine. Specifically, many commenters recommend the alternative of encouraging voluntary price reporting in DTC advertising, pursuant to the PhRMA Guiding Principles-Direct to Consumer Advertisements about Prescription Medicines. These guiding principles now recommend that prescription drug broadcast advertisements include direction to where patients can find information about the cost of the medicine, such as a company-developed website. Commenters note that this would provide the flexibility to include the most important information in a method that is most appropriate for patients. Commenters note that this approach would avoid some of the potential adverse consequences associated with the requirements of the final rule, and would meet the overall objectives of the policy of providing promoting price transparency for patients.

Response: We appreciate the commenters' recommendation to promote a program of voluntarily listing drug prices. However, we disagree that voluntary price disclosure would adequately meet the goals of providing price transparency. If price disclosure were voluntary, some manufacturers would decline to provide the list price to the patient, and the patient would therefore lack that valuable information. For the reasons stated elsewhere in this rule, we believe it is necessary to the efficient administration of Medicare and Medicaid that this information be disclosed in DTC television advertisements. In contrast, referring patients to other resources, such as company-owned websites, would not serve this purpose. First, it is likely that there would be a very low conversion of patients going to a website that is referenced in a TV ad that they see when they are not at their computer. More importantly, as noted in section II.D., 33 percent of adults surveyed say they do not frequently use the internet; as to the other, requiring them to open a browser, navigate to a site they saw on television, and click through to find pricing information creates additional burden and uncertain outcomes. Thus, manufacturer websites are not an adequate alternative to the price disclosure requirement we are finalizing in this final rule.

8. Use of Plan Finder

Comment: Some comments assert that CMS should develop its own database of list prices for the public to access.

Response: We continue to believe that the Medicare Part D Plan Finder is a valuable tool for patients, and we will continue to improve the tool over time through efforts such as the eMedicare Initiative.[44] We think the DTC television advertisement requirement provides additional information that is very useful to patients' understanding of drug pricing and provides important supplementary information to the Plan Finder tool.

Comment: Some comments stated that steps should be taken to encourage practitioners, plans, and payors to provide more information on prices and coverage.

Response: We agree that it is important to encourage health care practitioners, health plans, and payors to provide more information about prices and coverage. Price transparency is an important aspect of Medicare's most recent payment rules. In a recent proposed rule titled ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' which appeared in the **Federal Register** on November 30, 2018 (83 FR 62152), we proposed to require Part D sponsors to adopt Real-Time Pharmacy Benefits Tools (RTBT) and enhanced Explanation of Benefits (EOB) forms to provide beneficiaries and their prescribers with more drug price information. We continue to encourage all patient-facing stakeholders in the drug supply chain to educate their patients and incorporate the cost of drugs and biological products into all of the shared-decision making conversations to identify the best overall therapy for the patient.

F. Other Approaches

We also considered additional solutions to provide beneficiaries with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their OOP costs but also expenditures borne by Medicare and Medicaid. We sought comment on whether the following approaches could support price transparency and informed decision making, either in addition to or in lieu of the measures proposed in this notice of proposed rulemaking: (1.) An enhanced CMS drug pricing dashboard, (2.) intelligent plan selection or use of intelligent assignment, and (3.) a new payment code for drug pricing counseling. We are also interested in other approaches to price transparency and informed decision making that we have not contemplated.

1. Enhanced Drug Pricing Dashboard

Comment: Many commenters supported the development of a tool that could provide real-time information on drug costs, formulary, and cost-sharing that is easily accessible to patients. Some commenters pointed to useful examples in the private sector. Other commenters noted that PBMs and payors already have this capability. One commenter suggested that an enhancement could be to highlight drugs with excessive price increases or high prices, and list lower cost alternatives. Other commenters expressed general skepticism that a dashboard would be a useful tool for patients. First, commenters noted that there are existing private tools, such as GoodRx, that provide similar information. Next, commenters noted

[44] CMS News Room. CMS announces new streamlined user experience for Medicare beneficiaries. 2018 Oct 01. *https://www.cms.gov/newsroom/press-releases/cms-announces-new-streamlined-user-experience-medicare-beneficiaries-0.*

that dashboards, no matter how they are configured, are going to be complex and difficult for patients to use. While the information will be useful and interesting to researchers, it would likely provide limited value to patients.

Response: We appreciate these recommendations and agree that online information is no substitute for pricing information in the DTC ad itself. As discussed in section II.E.8., we recently proposed to require Part D sponsors to adopt a real time benefit tool (RTBT) that would provide information about drug costs, formulary placement and cost-sharing. In addition, we also recently enhanced the Medicare and Medicaid Drug spending dashboards [45] to identify the manufacturers of drugs with price increases and highlight year-over-year pricing information. We appreciate feedback sharing concern about the usefulness of the drug dashboard for patients. We will take this feedback into consideration as we continue to improve and enhance the drug dashboard.

2. Intelligent Plan Selection

Comment: Some commenters generally supported the development of a tool to support intelligent plan selection that is voluntary for patients, and recommended it as a general improvement. One commenter was concerned that such a tool would be difficult to implement. One commenter expressed concern that intelligent plan selection could lead to adverse selection of patients and potential market instability.

Response: We appreciate these recommendations and concerns. There are likely various operational issues that would need to be addressed as a threshold matter for such a tool to be feasible. If CMS were to pursue development of such a tool, we would need to consider and address such issues, as well as consider how to address commenters' concerns. We will continue to consider this concept.

3. Counseling Code

In an effort to incentivize provider engagement with patients on their prescription drug and biological product OOP costs, CMS could create a new payment code, in a budget neutral manner, for doctors to dialogue with patients on the benefits of drugs and drug alternatives. This would likely decrease the number of prescriptions that go unfilled because of unexpected high OOP costs, thus improving adherence, but also could increase provider awareness of drug pricing which may influence prescribing when appropriate cheaper options are available.

Comment: Some commenters recommend creating a new payment code for counseling on drug pricing to appropriately reimburse providers for the additional time that they will need to spend on discussing the cost of therapies for patients. One commenter supports creating a new code, but recommends that the code be broad enough to also reimburse providers for care planning and navigation, shared decision making, developing a plan of care, and fostering a care coordination process, which would include counseling patients on the potential costs of their drugs and biological products. A couple commenters that supported the creation of the new payment code recommended making this code available to pharmacists, who may be one of the best resources to provide this information to the patient. One commenter noted that providers will need real time access to cost data if they are expected to counsel patients on cost, so we should keep this in mind if we plan to create the code.

Other commenters recommend against creating a new payment code. One commenter noted that providers are not necessarily the ones that should be having these conversations because they do not always have access to the relevant drug pricing information. Instead, they recommend that payors provide this information to patients. Another commenter noted that most providers already counsel their patients on their OOP costs and the importance of filling their prescription, so it is not necessary to create a separate code. Another commenter notes that current E&M documentation guidelines are broad enough to cover these conversations as part of the risk and benefits of treatment options. Finally, many commenters, including those that generally support creating a new billing code are concerned where the resources would come from based on the budget neutral element of the code.

Response: We agree that services such as patient counseling, care planning and navigation, and shared decision making are valuable to patients and important for delivering high quality care. We also agree that pharmacists may be able to provide information on drug pricing and patient coinsurance to patients and advise patients on the availability of less expensive drugs in the event cost is a barrier to medication adherence. While we are not finalizing in this rule, we will consider a counseling code for future rulemaking in the appropriate benefit categories as allowed by statute.

G. Enforcement

We proposed in § 403.1204(a) that the Secretary will maintain a public list that will include the drugs and biological products identified by the Secretary to be advertised in violation of this rule. We expect that this information will be posted publicly on a CMS internet website no less than annually. No other HHS-specific enforcement mechanism was proposed. However, we anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act sec. 43(a), 15 U.S.C. 1125(a), for unfair competition in the form of false or misleading advertising. *See, e.g., POM Wonderful LLC* v. *Coca-Cola Co.,* 134 S. Ct. 2228, 2234 (2014); *In re McCormick & Co., Inc., Pepper Prod. Mktg. & Sales Practices Litig.* 215 F. Supp. 3d 51, 59 (D.D.C. 2016). Since Lanham Act cases normally involve sophisticated parties doing business in the same sector, the likelihood of meritless lawsuits is acceptably low. We sought comment on the primary enforcement mechanism and other approaches to enforcing compliance.

Under principles of implied preemption, to the extent State law makes compliance with both Federal law and State law impossible or would frustrate Federal purposes and objectives, the State requirement would be preempted. *See, e.g., Murphy* v. *NCAA,* 138 S. Ct. 1461, 1480–81 (2018); *Mutual Pharm. Co.* v. *Bartlett,* 570 U.S. 472, 480 (2013); *Geier* v. *American Honda Motor Co.,* 529 U.S. 861, 872–86 (2000). Obstacle preemption is not limited to examining the *accomplishment* of certain objectives; the *execution* is relevant as well. *Geier,* 529 U.S. 881–82. A state law is therefore preempted ''if it interferes with the methods by which the federal statute was designed to reach that goal.'' *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 103 (1992) (quoting *Int'l Paper Co.* v. *Ouellette,* 479 U.S. 481, 494 (1987)).

Because this proposed rule is part of a broader initiative to reduce the price to consumers of prescription drugs and biological products, it would be counterproductive if this rule were to increase transactional costs in defending meritless litigation. We believe that the existing authority cited above, namely the Lanham Act, is the appropriate mechanism for enforcing against deceptive trade practices. Accordingly, consistent with our not proposing any HHS-specific enforcement mechanism, we proposed at § 403.1204(b) that this

[45] Available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/index.html.*

rule preempt any state-law-based claim that depends in whole or in part on any pricing statement required by this rule.

1. Lanham Act

Comment: Several commenters were concerned that private actions under the Lanham Act would not be an adequate enforcement mechanism for the requirement that manufacturers include the current list price of a prescription drug or biological product in all DTC television advertisements. In particular, these commenters were concerned that standing to enforce this requirement would be limited to competitors, and that consumers, who have the greatest interest in receiving this pricing information, would be precluded from taking action against violators. A few commenters added that the high costs of pursuing an action under the Lanham Act would discourage companies from bringing claims, while one commenter expressed concern about the potential for higher drug costs due to drug manufacturers having to internalize the costs of Lanham Act litigation. Several commenters noted it would be difficult to prove a claim under the Lanham Act for false advertising solely on the basis of the omission of information regarding the list price of a prescription drug or biological product, which they assert differs from the price paid by most consumers. Some of these commenters also expressed concerns that a competitor would be unable to demonstrate commercial injury.

Response: We disagree with the comments asserting that the threat of private actions under the Lanham Act for unfair competition in the form of false or misleading advertising is not an appropriate mechanism to enforce the price disclosure requirement in § 403.1202. We acknowledge that standing to bring suit under the Lanham Act is limited to competitors and others that can allege an injury to a commercial interest, and consumers would not be able to challenge the omission of pricing information. *See Lexmark Int'l, Inc.* v. *Static Control Components, Inc.,* 572 U.S. 118, 132 134 S.Ct. 1377, 1390 (2014). We considered this limitation when proposing to rely upon the Lanham Act as the primary enforcement mechanism for the requirements of this rule. We continue to believe that competitors are best positioned to identify and act upon advertisements that violate this regulation. Furthermore, although consumers lack standing to bring an action under the Lanham Act, we note that a fundamental premise of the rules in section 43(a) of the Lanham Act is the strong public interest in protecting consumers from false and misleading advertising. *See Novartis Consumer Health, Inc.* v. *Johnson & Johnson-Merck Consumer Pharm., Co.,* 290 F.3d 578, 597 (3d Cir. 2002) (''[T]here is a strong public interest in the prevention of misleading advertisements . . . .'') (citations omitted); *Vidal Sassoon, Inc.* v. *Bristol Myers Co.,* 661 F.2d 272, 277 (2d Cir. 1981) (recognizing ''the clear purpose of Congress in protecting the consumer''). *See also,* Lillian R. BeVier, *Competitor Suits for False Advertising Under Section 43(a) of the Lanham Act: A Puzzle in the Law of Deception,* 78 Va. L. Rev. 1, 3 (1992) (''[T]he proper perspective from which to view the rules in section 43(a) cases is that of the potentially deceived consumer rather than the possibly injured competitor.''); Ross D. Petty, *Competitor Suits Against False Advertising: Is Section 43(a) of the Lanham Act a Proconsumer Rule or an Anticompetitive Tool?,* 20 U. Balt. L. Rev. 381, 395 (1991) (''Most courts recognize that there is a 'strong public interest' in using the Lanham Act to prevent misleading advertising and presume that consumers' as well as competitors' interests are to be protected under the Act.'') (citations omitted).

Although several commenters objected to our proposal to rely on Lanham Act actions by competitors to enforce the requirements of this rule on the grounds that such actions would be too costly, no commenters provided specific evidence that it would be prohibitively expensive to bring a Lanham Act suit. Indeed, if a competitor is able to establish a violation of section 43(a) of the Lanham Act, 15 U.S.C. 1125(a), and demonstrates that it has been injured as a result of that violation, it may be entitled to recover not only its own damages, but also the defendant's profits and the costs of the action. *See* 15 U.S.C. 1117(a). Furthermore, as we indicated in the proposed rule, because Lanham Act cases typically involve sophisticated parties doing business in the same sector, the likelihood of meritless lawsuits is acceptably low. As a result, the use of this enforcement mechanism is unlikely to force drug manufacturers to raise prices to account for the heavy costs of defending against meritless litigation.

Nor do we agree with those commenters who believe it will be impossible to demonstrate competitive harm from the omission of the required pricing information from a drug manufacturer's advertising. As noted by the commenters, a successful suit under section 43(a) of the Lanham Act, requires a ''false or misleading description of fact, or false or misleading representation of fact.'' 15 U.S.C. 1125(a). However, it is also well-established that a statement can be actionable under section 43(a) if it is ''affirmatively misleading, partially incorrect, or untrue *as a result of failure to disclose a material fact.*'' *See* 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* sec. 27.65 (5th ed. 2018) (citations omitted) (emphasis added). Failure to disclose the list price in a DTC advertisement, if required to do so by § 403.1202, makes that advertisement false and misleading. The disclosure requirements under § 403.1202 apply to all prescription drugs and biological products distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act other than ''excepted pharmaceuticals.'' Excepted pharmaceuticals are defined in § 403.1200(b) as any prescription drug or biological product that has a list price less than $35 per month for a 30-day supply or typical course of treatment. These excepted pharmaceuticals are exempt from the requirement to disclose pricing information in their advertisements. As a result, when an advertisement does not include pricing information, it would be reasonable for a consumer to conclude that the prescription drug or biological product is an excepted pharmaceutical, with a list price of less than $35. Thus, the omission of pricing information from an advertisement for a higher cost pharmaceutical is inherently false and misleading.

Finally, we disagree that it will be impossible for a competitor to show harm arising from the omission of information regarding the list price of a prescription drug or biological product from an advertisement. Commenters asserted this would be the case because the list price does not reflect the actual purchase price that will be paid by all consumers for all purchases. However, as discussed above, there is a direct link between the WAC and the price paid for the majority of patients, including any uninsured patients and patients with high-deductible health plans, or co-insurance, including Part D. Disclosure of the list price substantially affected consumer interest in high-priced drugs. In contrast, price disclosures had little influence on consumer interest in low-priced drugs.[46] Thus, it is reasonable to believe that the omission of list price information for a particular prescription

[46] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019; 179(3): 435–437. (''2019 JAMA Study'').

drug or biological product, which would imply that the drug or biologic is in the low-priced category of excepted pharmaceuticals, could be material to a consumer's decision to choose that prescription drug or biological product, rather than a competing product that includes a higher list price in its advertising, as required under § 403.1202. *See McCormick & Co, Inc., Pepper Prod. Mktg. & Sales Practices Litig.,* 215 F. Supp. 3d 51, 57 (D.D.C. 2016)(''[I]t is the stuff of the most elementary economic texts that if two firms are offering a similar product for different prices, the firm offering the lower price will draw away customers from its competitor.'') (quoting *Am. Soc'y of Travel Agents, Inc.* v. *Blumenthal,* 566 F.2d 145, 157 (D.C. Cir. 1977) (Bazelon, C.J., dissenting)). Furthermore, the Lanham Act can be an effective enforcement tool even in the absence of direct evidence of lost sales or other competitive injury. Courts have held that there is no requirement that a competitor prove direct injury in order to bring an action to enjoin conduct that violates section 43(a) of the Lanham Act. *See, e.g., Porous Media Corp.* v. *Pall Corp.,* 110 F.3d 1329, 1335 (8th Cir. 1997) (''A plaintiff suing to enjoin conduct that violates the Lanham Act need not prove specific damage.''); *Southland Sod Farms* v. *Stover Seed Co.,* 108 F.3d 1134, 1145 (9th Cir. 1997). Thus, even if a manufacturer were unable to prove direct injury from the omission of accurate pricing information from a competitor's advertisement, it would not be precluded from bringing an action under the Lanham Act seeking to enjoin the competitor from continued use of that false or misleading advertisement.

2. State Preemption

Comment: Three commenters had comments on proposed § 403.1204(b), preempting the exercise of State laws based on the pricing statement required in the proposed rule. One commenter stated that remedies under State law, particularly those that could be accessed by consumers, should be available as a supplement to the Lanham Act remedy cited in the proposed rule with respect to information revealed as a result of the pricing statement required in the proposed rule. Two other commenters supported the transparency provisions of the proposed rule, but asked that CMS clarify that these provisions represent a ''floor,'' such that State laws that impose transparency requirements that go further than those in the proposed rule should not be pre-empted.

Response: As noted in the preamble to the proposed rule, we believe that the Lanham Act is the appropriate mechanism for addressing improper drug manufacturer practices that may be revealed as the result of the reporting required by this rule. We remain concerned that the pricing statement required under this final rule could give rise to the use of State law requirements or remedies in a manner that could result in litigation costs involving potentially meritless cases that could defeat the goal of this rule of lowering drug prices. We appreciate the comment for highlighting a potential ambiguity in the proposed preemption provision. We do not intend for this rule to create an environment where states would impose varying disclosure requirements on television advertisements that may air in each respective state. We did not intend that the rule would create a regulatory ''floor.'' To ensure that prescription pharmaceutical advertisements on television would not have to vary from state to state, we have modified the preemption language at § 403.1204(b) as set out in the regulatory text at the end of this rule.

3. Alternative Enforcement Mechanisms

We sought comment on whether compliance with this rule should be a condition of payment, directly or indirectly, from these federal health care programs.

Comment: Several commenters suggested that CMS consider additional enforcement mechanisms, including ones the government could initiate, to ensure compliance with the requirement to disclose drug pricing information. Some of these commenters also responded directly to our request for comments as to whether compliance with this rule should be a condition of payment, directly or indirectly, under Medicare and Medicaid, by asserting that such a requirement would be more effective than either the public list or the threat of lawsuits under the Lanham Act. One commenter agreed that making compliance a condition of either coverage or payment would be a stronger enforcement mechanism, but noted that pursuing either of these options would require a change in law.

Response: We thank the commenters for their suggestions. For the reasons explained previously, we continue to believe that posting a list of drugs and biological products identified by the Secretary to be advertised in violation of this final rule on the CMS internet website, coupled with the threat of private actions under the Lanham Act for false or misleading advertising, is the most appropriate approach to enforcing the requirements of this final rule. In reaching this conclusion, we carefully evaluated the alternative of making compliance with this rule a condition of payment under Medicare and Medicaid, including the comments recommending this approach. At this time, we do not believe that more stringent regulation is warranted, but will continue to assess compliance. If there is absence of robust compliance, then the Secretary will re-evaluate potential options and consider further rulemaking in this area.

In summary, we are finalizing this rule as proposed, except for the technical changes to § 403.1202 described above to improve clarity, the modification at § 403.1204(b) in response to comments, and technical changes to §§ 403.1201(d) and 403.1204(a) to use defined terms.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. We solicited public comment on the issues in this document that contain information collection requirements (ICRs).

Comment: Some comments assert that the rule would be unduly burdensome in that it would clutter the advertisement and would require monthly updates.

Response: Please see the response to comments on the burden of the rule in Section II.D.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupation code	Mean hourly wage ($/hr)	Adjusted hourly wage ($/hr)
Office and Administrative Support Occupations	43–0000	$17.91	$35.82
Marketing and Sales Managers	11–2020	66.52	133.04
Lawyers	23–1011	67.25	134.50

B. Information Collection Requirements Regarding Pricing Information (§ 403.1202)

Section 403.1202 requires that advertisements for certain prescription drug or biological products on television (including broadcast, cable, streaming, and satellite), contain a statement or statements indicating the Wholesale Acquisition Cost (referred to as the list price) for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. The presentation of this information must appear in a specific format. As stated in this final rule, the notification must be presented as follows, ''The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.''

We estimate that 25 pharmaceutical companies will run an estimated 300 distinct pharmaceutical advertisements that appear on television each quarter and will be affected by this rule. For these advertisements, we estimate that administrative support staff and marketing managers will need to verify the prescribed language and that the correct price appears in each advertisement each quarter.

We estimate that this will require 10 minutes and $5.97 ($35.82/hr × .167) per advertisement for administrative support staff. We also estimate five minutes and $11.09 ($133.04/hr × .083) per advertisement for marketing managers, for a total of 15 minutes (0.25 hours) and $17.06 ($5.97 + $11.09) per advertisement per quarter or 300 hours per year across all pharmaceutical companies running affected televised advertisements ((300 ads/quarter) × (4 quarters/year) × (.25 hours/ad)). As a result, using wage information provided in Table 2, we estimate costs of $20,472 (1,200 ads × $17.06/ad) per year in each year following publication of the final rule after adjusting for overhead and benefits.

We are in the process of obtaining OMB approval for the aforementioned information collection requirements. Subsequent to the proposed rule, we published a separate 60-day **Federal Register** notice announcing the proposed information collection activity and soliciting comments. The 60-day notice published on April 8, 2019 (84 FR 13929) and also instructs the public on how to obtain copies of the information collection request (ICR) for review and comment. We will also publish a separate 30-day notice to announce the formal submission the ICR to OMB. At that time, the public will have an additional opportunity to review and submit comments on the ICR. These requirements are not effective until they have been approved by the OMB.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule aims to improve the quality, accessibility and affordability of the Medicare and Medicaid programs and to improve the CMS customer experience by providing transparency into drug prices with the goal of reducing the price to beneficiaries of certain prescription drugs and biological products. Currently, consumers have incomplete information regarding the cost of pharmaceutical products. As a result, they lack important information needed to inform their decisions, which likely leads to inefficient utilization of prescription drugs or biological product. This rule requires disclosure of prices to the general public for prescription drug and biological products advertised on television. This may improve awareness and allow the general public to respond, potentially increasing the efficiency of prescription drug or biological product utilization. While we expect this rule to put downward pressure on the list prices of drugs, we cannot quantify the level of this impact because there is not data or examples that we can use.

B. Overall Impact

We acknowledge that examination of the impact of this final rule is required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the (RFA) (September 19, 1980, Pub. L. 96–354), Section 1102(b) of the Social Security Act, Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L., Public Law 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The Regulatory Flexibility Analysis (RFA), as amended, requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least five percent of small entities experience an impact of more than three percent of revenue. As discussed in the impact analysis, we calculate the administrative costs (excluding opportunity costs of screen time newly dedicated to displaying pricing information) of the changes per affected business over 2020–2024. The estimated average administrative costs of the rule per business peak in 2020 at approximately $2,900, and are approximately $1,300 in subsequent years. We note that relatively large entities are likely to experience proportionally higher costs. As discussed below, total administrative costs of the rule are estimated to be $5.2 million in 2020 and $2.4 million in subsequent years. According to the U.S. Census, 1,775 pharmaceutical and medicine manufacturing firms operating in the U.S. in 2015 had annual payroll of $23.2 billion. Since the estimated administrative costs of this proposed rule are a tiny fraction of payroll for covered entities, the Department concludes that the rule will not have a significant economic impact on a substantial number of small entities and the Secretary so certifies.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation under Title XVIII, Title XIX, or Part B of the Act that may have significant impact on the operations of a substantial number

of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending that may result in expenditures in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $154 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, of $154 million or more. Going forward, we believe that this rule will not impose mandates on the private sector that would result in an expenditure that exceeds the UMRA ceiling.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirements or costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since reviewing this rule does not impose any substantial costs on state or local governments, under the requirements threshold criteria of Executive Order 13132 are not applicable, we have determined that this rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Office of Management and Budget has determined that this is an economically significant regulatory action. In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

This final rule is considered an Executive Order 13771 (January 30, 2017) regulatory action. We estimated that it will impose $2.45 million in annualized costs at a seven percent discount rate, discounted to a 2016 equivalent, over a perpetual time horizon.

Comment: One commenter stated that the proposed rule's impact analysis was flawed because it did not show that consumers lack adequate information about list prices for prescription drugs or biological products and overlooked costs to consumers and manufacturers. The commenter recommended that CMS more clearly identify a market failure that would be addressed by the rule; more thoroughly assess the rule's costs; more thoroughly review available literature on the effects of mandatory price disclosure in pharmaceutical markets; and conduct its own studies of the rule's potential effects on consumer and manufacturer behavior.

Response: We disagree that consumers currently have adequate information on list prices for prescription drugs or biological products, because they do not have readily available access to prescription drug or biological product prices. Though some variation of drug prices are available online, we have shown that consumers are not currently effectively using these online resources to find this information or identify health insurance products and treatments that are most cost effective for the patient.[47] We have also shown that including the price in DTC changes patient behavior, showing that making the information easily available provides valuable information that patients would use for decision making.[48] Finally, we have seen that 88 percent of Americans (*i.e.,* consumers) want the prices to be listed in DTC advertisements, showing that even though the prices may be available through other sources, such as online, it is important to them to have the prices listed on advertisements to have the valuable information readily accessible.[49] We believe that we have identified a market failure and assessed the rule's cost. We believe that it is unnecessary to pilot the intervention in this rule because a recent study previews the potential impact of the rule. Furthermore, one pharmaceutical company conducted their own research and ultimately decided to proceed on their own in the absence of regulation. It is unclear how a small-scale pilot would provide additional information that would support changing the policy. As discussed above, studies have shown patient responses to list prices being included in DTC television advertisements and shown that many effects (including adverse effects) can be mitigated through disclaimers such as the one included in this rule. Additionally, manufacturers are free to add additional statements to their advertisements addressing these concerns.

C. Anticipated Effects

This rule will affect the operations of prescription drug or biological product manufacturers. According to the U.S. Census, there were 1,775 pharmaceutical and medicine manufacturing firms operating in the U.S. in 2015.[50] We estimate that this rule will require individuals employed by these entities to spend time in order to comply with these regulations. We estimate the hourly wages of individuals affected by this rule using the May 2017 National Occupational Employment and Wage Estimates provided by the U.S. Bureau of Labor Statistics. We assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. We note that, throughout, estimates are presented in 2016 dollars. We use the wages of Lawyers as a proxy for legal staff, the wages of Marketing and Sales Managers as a proxy for marketing management staff, and Office and Administrative Support Occupations as a proxy for administrative support staff. Estimated hourly rates for all relevant categories are included in Table 3 below.

TABLE 3—HOURLY WAGES

Marketing and Sales Managers	$66.52
Lawyers	67.25
Office and Administrative Support Occupations	17.91

1. Direct Staff Costs of Implementation

We expect that the costs associated with the initial review by all companies of the policy, an ongoing review by all companies to ensure that they are in compliance with the policy, and the individual review of commercials for companies that produce DTC television advertisements.

(a) Initial Review After Publication

In order to comply with the regulatory changes adopted in this rule, affected businesses would first need to review the rule. We estimate that this would require an average of two hours for affected businesses to review, divided evenly between marketing managers and

[47] Zhou C and Zhang Y. The vast majority of Medicare Part D beneficiaries still don't choose the cheapest plans that meet their medication needs. Health Aff. 2012 Oct;31(10):2259–65.

[48] Garrett JB, Tayler WB, Bai G, et al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''2019 JAMA Study'').

[49] Kirzinger A, Lopes L, We B, and Brodie M. KFF Health Tracking Poll—February 2019: Prescription Drugs. Kaiser Family Foundation. 2019 March 01. *https://www.kff.org/8c7d090/.*

[50] U.S. Census. 2015 SUSB Annual Data Tables by Establishment Industry. *https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html.*

lawyers, in the first year following publication of the final rule. As a result, using wage information provided in Table 2, this implies costs of $474,884 in the first year following publication of a final rule after adjusting for overhead and benefits.[51]

(b) Initial and Ongoing Compliance

After reviewing the rule, prescription drug or biological product manufacturers will review their marketing strategies in the context of these new requirements, and determine how to respond. For some affected entities, this may mean substantially changing their advertising paradigm or pricing strategy. For others, much more modest changes are likely needed. We estimate that this would result in affected businesses spending an average of 20 hours reviewing their policies and determining how to respond, with 5 hours spent by lawyers and 15 hours spent by marketing managers, in the first year following publication of the final rule. In subsequent years, we estimate this would result in marketing managers at affected businesses spending an average of 10 hours implementing policy changes. As a result, using wage information provided in Table 2, we estimate costs of $4.74 million in the first year[52] and $2.36 million in subsequent years[53] following publication of this final rule after adjusting for overhead and benefits.

(c) Direct Advertisement Review

We estimate that 25 pharmaceutical companies will run an estimated 300 distinct pharmaceutical advertisements that appear on television each quarter and will be affected by this rule. For these advertisements, we estimate that administrative support staff and marketing managers will need to verify the prescribed language and that the correct price appears in each advertisement each quarter. We estimate that this will require 10 minutes and $5.97 ($35.82/hr × .167) per advertisement for administrative support staff. We also estimate five minutes and $11.09 ($133.04/hr × .083) per advertisement for marketing managers, for a total of 15 minutes (0.25 hours) and $17.06 ($5.97 + $11.09) per advertisement per quarter or 300 hours per year across all pharmaceutical companies running affected televised advertisements ((300 ads/quarter) × (4 quarters/year) × (.25 hours/ad)). As a result, using wage information provided in Table 2, we estimate costs of $20,472 (1200 ads × $17.06/ad) per year in each year following publication of the final rule after adjusting for overhead and benefits.

2. Direct Costs for Changes to Advertisements

We may also want to consider the opportunity costs for the space in the advertisement that includes the list price that could have been used for other purposes. A reasonable estimate is that compliance requires 1percent of the screen space and four seconds of a 75-second commercial. That means that the opportunity cost attributable could be approximately $2.24 million = (1% × 4/75 × $4.2 billion DTC television advertising spending). We note that current DTC television advertisements currently use space to refer patients to their website for additional information, and that same space can include that website and include the list price as a reference (*i.e.,* the advertisements could provide this information in the space that is already dedicated to referring patients to additional information).

In markets for prescription drugs and biological products, consumers often need to make decisions with incomplete information about prices. As a result, consumers are unable to make decisions that best suit their needs. This rule may improve price transparency for consumers in order to ensure that their decisions better align with their preferences and their budget, potentially improving the allocation of resources in the prescription drug market. On the other hand, consumers, intimidated and confused by high list prices, may be deterred from contacting their physicians about drugs or medical conditions. Consumers might believe they are being asked to pay the list price rather than a co-pay or co-insurance and wonder why they are paying so much when they already paid a premium for their drug plan. This could discourage patients from using beneficial medications, reduce access, and potentially increase total cost of care. We lack data to quantify these effects.

In addition, we believe that this rule may provide a moderating force to counteract prescription drug or biological product price increases. This rule will provide direct evidence of prescription drug or biological product prices to the general public, potentially improving awareness and allowing the general public to signal in some cases that prescription drug or biological product prices have risen beyond their willingness to pay. We believe that this, in turn, may further improve the rule's effect on the efficient utilization of prescription drugs or biological products. We lack data to quantify these effects.

We believe that this rule may also have impacts along other dimensions. In particular, it may affect the number of televised DTC advertisements, the rate at which televised DTC advertisements are updated, prices for prescription drugs or biological products, the set of pharmaceutical products available for sale, and utilization of various prescription drugs or biological products. A possibility not reflected in the quantitative estimates above is that drug companies would find the cost of revising their advertisements to be prohibitively expensive (for example, if they change their WACs so frequently that there is extensive monitoring and revision necessary to ensure that advertisements airing on a particular day match the WAC for that day). In this case, DTC television advertising would be reduced. However, we think this is unlikely as prices are usually changed on a twice-a-year cycle, and manufacturers may already frequently revise their advertisements to align with quarterly marketing plans. We requested comment, but did not get any comments, on the following questions:

- What is the frequency with which WACs are changed?
- What would be the effect of this potential advertising reduction on patient behavior, including as regards the information they seek out from their medical providers?
- How might patient outcomes vary depending on advertising choices among competitor drug companies? For example, if only some producers of drugs that treat a particular condition cease advertising on television, are patients likely to switch between drug brands—from the no-longer-advertised to the advertised? If all producers of drugs for a condition cease advertising on television, to what extent are patients likely to switch to other forms of treatment—such as surgery—or to forgo treatment?
- To what extent will drug companies, in order to increase the feasibility of continuing to advertise on television, reduce the frequency of changing their WACs? What would be the consequences for drug supply chains and the prices experienced by patients and other payors?

Furthermore, the Department recognizes that some studies indicate DTC advertising increases disease awareness, and that if this rule decreases disease awareness such that

[51] 1,755 firms × (1 hour of legal work × 200% × $67.25 + 1 hour of marketing work × 200% × $66.52) = $474,884.

[52] 1,775 firms × (5 hours of legal work × 200% × $67.25 + 15 hours of marketing work × 200% × $66.52) = $4,735,878.

[53] 1,775 firms × (10 hours of marketing work × 200% × $66.52) = $2,361,460.

untreated illness occurs, there may be other impacts. We lack data to quantify the effects of this rule along these dimensions.

Comment: One commenter suggested that the RIA overlooks the costs to pharmaceutical industry due to potential lost sales.

Response: We disagree with this comment because there is no clear evidence that posting the list price will adversely affect sales. As discussed in Section II.C., including a disclaimer that the drug could be available at a lower price, such as the wording we include in this rule, mitigate patient concerns about price. This rule makes the patient a more informed consumer. At the same time, the information is not expected to cause patients to forgo treatment. Instead, patients may select the lowest cost alternative, so the revenue is still going into the industry as a whole. It may be a transfer from high cost drugs to their marginally lower cost alternatives. Additionally, as discussed above, it is difficult to predict exactly how the industry will respond, but one potential is that their list prices are lowered closer to their net price, so while the list price would go down, it would not necessarily affect the revenue going into the industry.

Comment: One commenter suggested that we overlooked potential costs to consumers based on their behavior changes, such as choosing to forgo treatment.

Response: We disagree with this comment for the same reason we disagree with the above comment. The 2019 JAMA Study showed that including a stipulation that the medication could be available at a lower price mitigates potential adverse, unintended consequences,[54] so we do not expect patients to choose to forego treatment. Instead, we expect them to become informed consumers that engage in shared-decision making with their providers, which may allow them to select the lowest cost alternative based on their specific situation. This can reduce the cost to the patient while increasing revenue to some manufacturers in reducing the revenue to others.

D. Alternatives Considered

We carefully considered the alternative of maintaining the status quo and not pursuing regulatory action. However, we believe that the price transparency is fundamental to ensuring that prescription drug and biological product markets function properly. This rule may improve price transparency in order for consumers to make better decisions. As a result, we have determined that the benefits of the rule justify the costs imposed on industry, and as a result we chose to pursue this regulatory action.

We also carefully considered requiring the disclosure of alternative or additional prices, which better reflect the actual costs paid by patients and payors. If an alternative definition were used for list price, the burden imposed by the rule would likely be higher. For example, manufacturers set the Wholesale Acquisition Cost, also known as list price, for their products. The Department recognizes that other prices may be paid by distributors, pharmacies, patients, and others in the supply chain. Because these other prices vary by contracts established by payors or others, only the WAC is certain to be known by the manufacturer when creating DTC advertisements. As such, it would be harder for manufacturers to report prices other than Wholesale Acquisition Cost. We believe that requiring the disclosure of WAC minimizes administrative burden among feasible alternatives and balances the need to provide information to the general public.

E. Accounting Statement

TABLE 3—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL PROPOSED CHANGES

	Present value over 2020–2024 by discount rate (millions of 2016 dollars)		Annualized value over 2020–2024 by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Benefits:				
Quantified Benefits	0	0	0	0
Non-quantified Benefits.				
Improved transparency for prescription drug and biological product prices.				
Costs:				
Quantified Costs	25.6	23.1	6.1	6.8
Non-quantified Costs Due to Lack of Data.				
Costs based on resulting changes in drug prices.				
Costs based on potential changes in manufacturer behavior based on perceived value of DTC advertising.				
Costs based potential changes in patient and provide behavior.				

List of Subjects in 42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 2. Subpart L is added to read as follows:

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

Sec.
403.1200 Scope.
403.1201 Definitions.
403.1202 Pricing information.
403.1203 Specific presentation requirements.
403.1204 Compliance.

[54] Garrett JB, Tayler WB, Bai G, et. al. Consumer Responses to Price Disclosure in Direct-to-Consumer Pharmaceutical Advertising. JAMA Intern Med. 2019;179(3):435–437. (''JAMA 2019 Study'').

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

§ 403.1200 Scope.

(a) *Covered pharmaceuticals.* Except as specified in paragraph (b) of this section, this subpart applies to advertisements for a prescription drug or biological product distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act.

(b) *Excepted pharmaceuticals.* An advertisement for any prescription drug or biological product that has a list price, as defined in § 403.1201, less than $35 per month for a 30-day supply or typical course of treatment shall be exempt from the requirements of this subpart.

§ 403.1201 Definitions.

For the purposes of this subpart, the following definitions apply:

(a) *Biological product.* Biological product means any biological product, as that term is defined in Public Health Service Act (''PHS Act'') section 351(i), that is licensed by the Food and Drug Administration pursuant to section 351 and is subject to the requirements of Federal Food, Drug, and Cosmetic Act (FDCA) section 503(b)(1).

(b) *Prescription drug.* Prescription drug means any drug, as defined in the FDCA section 201(g), that has been approved by the Food and Drug Administration pursuant to FDCA section 505 and is subject to the requirements of FDCA section 503(b)(1).

(c) *List price.* List price means the wholesale acquisition cost, as defined in paragraph (d) of this section.

(d) *Wholesale acquisition cost.* Wholesale acquisition cost means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

§ 403.1202 Pricing information.

Any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: ''The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.'' Where the price is related to the typical course of treatment and that typical course of treatment varies depending on the indication for which a prescription drug or biological product is prescribed, the list price to be used is the one for the typical course of treatment associated with the primary indication addressed in the advertisement.

§ 403.1203 Specific presentation requirements.

The textual statement described in § 403.1202 shall be presented at the end of an advertisement in a legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

§ 403.1204 Compliance.

(a) *Identification of non-compliant products.* The Secretary will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation of this subpart.

(b) *State or local requirements.* No State or political subdivision of any State may establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by this subpart.

Dated: April 25, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–09655 Filed 5–8–19; 8:45 am]

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FEDERAL REGISTER

Vol. 84 Friday,

No. 91 May 10, 2019

Part IV

The President

Executive Order 13871—Imposing Sanctions With Respect to the Iron, Steel, Aluminum, and Copper Sectors of Iran

Federal Register
Vol. 84, No. 91
Friday, May 10, 2019

Presidential Documents

Title 3—

The President

Executive Order 13871 of May 8, 2019

Imposing Sanctions With Respect to the Iron, Steel, Aluminum, and Copper Sectors of Iran

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code, I, DONALD J. TRUMP, President of the United States of America, find that:

It remains the policy of the United States to deny Iran all paths to both a nuclear weapon and intercontinental ballistic missiles, and to counter the totality of Iran's malign influence in the Middle East. It is also the policy of the United States to deny the Iranian government revenue, including revenue derived from the export of products from Iran's iron, steel, aluminum, and copper sectors, that may be used to provide funding and support for the proliferation of weapons of mass destruction, terrorist groups and networks, campaigns of regional aggression, and military expansion.

In light of these findings and in order to take further steps with respect to the national emergency declared in Executive Order 12957 of March 15, 1995, and to supplement the authorities provided in the Iran Freedom and Counter-Proliferation Act of 2012 (subtitle D of title XII of Public Law 112–239), I hereby order:

Section 1. (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in: any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(i) to be operating in the iron, steel, aluminum, or copper sector of Iran, or to be a person that owns, controls, or operates an entity that is part of the iron, steel, aluminum, or copper sector of Iran;

(ii) to have knowingly engaged, on or after the date of this order, in a significant transaction for the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran;

(iii) to have knowingly engaged, on or after the date of this order, in a significant transaction for the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran;

(iv) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of any person whose property and interests in property are blocked pursuant to this section; or

(v) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this section.

(b) The prohibitions in this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be

issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 2. (a) The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to impose on a foreign financial institution the sanctions described in subsection (b) of this section upon determining that the foreign financial institution has, on or after the date of this order, knowingly conducted or facilitated any significant financial transaction:

(i) for the sale, supply, or transfer to Iran of significant goods or services used in connection with the iron, steel, aluminum, or copper sectors of Iran;

(ii) for the purchase, acquisition, sale, transport, or marketing of iron, iron products, aluminum, aluminum products, steel, steel products, copper, or copper products from Iran; or

(iii) for or on behalf of any person whose property and interests in property are blocked pursuant to this order.

(b) With respect to any foreign financial institution determined by the Secretary of the Treasury in accordance with this section to meet any of the criteria set forth in subsection (a)(i) through (a)(iii) of this section, the Secretary of the Treasury may prohibit the opening, and prohibit or impose strict conditions on maintaining, in the United States of a correspondent account or payable-through account by such foreign financial institution.

(c) The prohibitions in subsection (b) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 3. I hereby determine that the making of donations of the types of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this order would seriously impair my ability to deal with the national emergency declared in Executive Order 12957, and I hereby prohibit such donations as provided by this section.

Sec. 4. The prohibitions in section 1 of this order include:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to subsection (a) of that section; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 5. The unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the criteria in subsection 1(a) of this order would be detrimental to the interests of the United States, and the entry of such persons into the United States, as immigrants or nonimmigrants, is therefore hereby suspended. Such persons shall be treated as persons covered by section 1 of Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions).

Sec. 6. (a) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 7. Nothing in this order shall apply to transactions for the conduct of the official business of the Federal Government or the United Nations (including its specialized agencies, programmes, funds, and related organizations) by employees, grantees, or contractors thereof.

Sec. 8. For the purposes of this order:

(a) the term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization;

(b) the term ''foreign financial institution'' means any foreign entity that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes, but is not limited to, depository institutions, banks, savings banks, money service businesses, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, dealers in precious metals, stones, or jewels, and holding companies, affiliates, or subsidiaries of any of the foregoing. The term does not include the international financial institutions identified in 22 U.S.C. 262r(c)(2), the International Fund for Agricultural Development, the North American Development Bank, or any other international financial institution so notified by the Secretary of the Treasury;

(c) the term ''Government of Iran'' includes the Government of Iran, any political subdivision, agency, or instrumentality thereof, including the Central Bank of Iran, and any person owned or controlled by, or acting for or on behalf of, the Government of Iran;

(d) the term ''Iran'' means the Government of Iran and the territory of Iran and any other territory or marine area, including the exclusive economic zone and continental shelf, over which the Government of Iran claims sovereignty, sovereign rights, or jurisdiction, provided that the Government of Iran exercises partial or total de facto control over the area or derives a benefit from economic activity in the area pursuant to international arrangements;

(e) the term ''knowingly,'' with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result;

(f) the term ''person'' means an individual or entity; and

(g) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

Sec. 9. For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in Executive Order 12957, there need be no prior notice of a listing or determination made pursuant to section 1 of this order.

Sec. 10. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including adopting rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to implement this order. The Secretary of the Treasury may, consistent with applicable law, redelegate any of these functions within the Department of the Treasury. All agencies shall take all appropriate measures within their authority to implement this order.

Sec. 11. (a) Nothing in this order shall be construed to impair or otherwise affect:

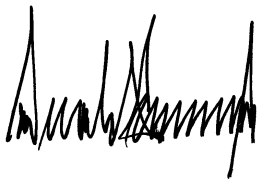
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 12. The measures taken pursuant to this order are in response to actions of the Government of Iran occurring after the conclusion of the 1981 Algiers Accords, and are intended solely as a response to those later actions.



THE WHITE HOUSE,
May 8, 2019.

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