FEDERAL REGISTER

Vol. 83 Thursday,

No. 183 September 20, 2018

Pages 47547–47800

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

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

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

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Contents

Federal Register

Vol. 83, No. 183

Thursday, September 20, 2018

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 83, No. 183
Thursday, September 20, 2018

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

The Code of Federal Regulations is sold by the Superintendent of Documents.

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1653

Tax Withholding on Court Ordered Payments

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Direct final rule.

SUMMARY: This rule deletes regulatory language that provides for the Federal income tax withholding rates on court ordered payments from the Thrift Savings Plan.

DATES: This rule is effective without further action on October 22, 2018, unless significant adverse comment is received by October 15, 2018. If significant adverse comment is received, the FRTIB will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments using one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Office of General Counsel, Attn: Megan G. Grumbine, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002.
- *Hand Delivery/Courier:* The address for sending comments by hand delivery or courier is the same as that for submitting comments by mail.
- *Facsimile:* Comments may be submitted by facsimile at (202) 942–1676.

The most helpful comments explain the reason for any recommended change and include data, information, and the authority that supports the recommended change.

FOR FURTHER INFORMATION CONTACT: Laurissa Stokes at (202) 942–1645.

SUPPLEMENTARY INFORMATION: The FRTIB administers the Thrift Savings Plan (TSP), which was established by the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514. The TSP provisions of FERSA are codified, as amended, largely at 5 U.S.C. 8351 and 8401–79. The TSP is a tax-deferred retirement savings plan for Federal civilian employees and members of the uniformed services. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)).

Currently, paragraph (e) of 5 CFR 1635.5 specifies the person to whom a court ordered payment from the TSP may be made and, in addition, specifies the Federal income tax withholding rates on such payments. This rule deletes the language that specifies the Federal income tax withholding rates on court ordered TSP payments.

The Federal income tax withholding rates on all TSP payments are dictated by the Internal Revenue Code. As such, any FRTIB regulatory language that expresses the withholding rates are, at best, duplicative of the Internal Revenue Code. The Federal income tax withholding rates required by the Internal Revenue Code are more appropriately communicated to participants and beneficiaries via the TSP website or via forms and publications provided directly to them.

Type of Rulemaking

In a direct final rulemaking, an agency publishes a direct final rule in the **Federal Register** along with a statement that the rule will become effective unless the agency receives significant adverse comment within a specified period. The FRTIB is using a direct final rule for this rulemaking because it expects this regulation to be noncontroversial. The FRTIB will withdraw the rule if it receives significant adverse comment. Comments that are not adverse may be considered for modifications to part 1653 at a future date. If no significant adverse comment is received, the rule will become effective without additional action.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will affect Federal employees and members of the uniformed services who participate in the Thrift Savings Plan, which is a Federal defined contribution retirement savings plan created under the Federal Employees' Retirement System Act of 1986 (FERSA), Public Law 99–335, 100 Stat. 514, and which is administered by the FRTIB.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the criteria of the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, 1501–1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under section 1532 is not required.

Submission to Congress and the General Accounting Office

Pursuant to 5 U.S.C. 810(a)(1)(A), the Agency submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States before publication of this rule in the **Federal Register**. This rule is not a major rule as defined at 5 U.S.C. 814(2).

List of Subjects in 5 CFR Part 1653

Alimony, Child support, Government employees, Pensions, Retirement.

Ravindra Deo,

Executive Director, Federal Retirement Thrift Investment Board.

For the reasons stated in the preamble, the Agency amends 5 CFR chapter VI as follows:

PART 1653—COURT ORDERS AND LEGAL PROCESSES AFFECTING THRIFT SAVINGS PLAN ACCOUNTS

■ 1. The authority citation for part 1653 continues to read as follows:

Authority: 5 U.S.C. 8432d, 8435, 8436(b), 8437(e), 8439(a)(3), 8467, 8474(b)(5) and 8474(c)(1).

■ 2. Amend § 1653.5 by revising paragraph (e) to read as follows:

§ 1653.5 Payment.

* * * * *

(e) Payment will be made only to the person or persons specified in the court order. However, if the court order specifies a third-party mailing address for the payment, the TSP will mail to the address specified any portion of the payment that is not transferred to a traditional IRA, Roth IRA, or eligible employer plan.

* * * * *

[FR Doc. 2018–20471 Filed 9–19–18; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No.: FAA–2014–1027; Amdt. No. 25–146]

RIN 2120–AK24

Transport Airplane Fuel Tank and System Lightning Protection

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is amending certain airworthiness regulations for transport category airplanes regarding lightning protection of fuel systems. This action is relieving in several ways. It removes the requirement for manufacturers to provide triple-redundant fault tolerance in lightning protection. It removes regulatory inconsistency by establishing a single standard for lightning protection of both fuel tank structure and fuel tank systems. It establishes a performance-based standard that the design and installation of fuel systems prevent catastrophic fuel vapor ignition caused by lightning and its effects. This performance-based standard allows applicants to choose how to provide the required level of safety. This action requires airworthiness limitations to preclude the degradation of design features that prevent catastrophic fuel vapor ignition caused by lightning. Its intended effects are to align airworthiness standards with industry's and the FAA's understanding of lightning, and to address issues of inconsistency and impracticality that applicants experienced with previous lightning protection regulations.

DATES: Effective November 19, 2018.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How To Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions concerning this action, contact Stephen Slotte, Airplane and Flight Crew Interface Section, AIR–671, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax (206) 231–3163; email *steve.slotte@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General Requirements.'' Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for the design and performance of aircraft that the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority. It prescribes revised safety standards for the design and operation of transport category airplanes.

I. Overview of Final Rule

The FAA is amending the airworthiness regulations in title 14, Code of Federal Regulations (14 CFR) part 25 related to the lightning protection of fuel systems [1] (including fuel tank structure [2] and fuel tank systems [3]). This amendment removes the requirement for prevention of lightning ignition sources from § 25.981(a)(3), ''Fuel tank ignition prevention,'' at amendment 25–102 and modifies § 25.954, ''Fuel system lightning protection.'' The modification to § 25.954 creates a performance-based standard that provides definitions for ''critical lightning strike'' and ''fuel systems;'' requires catastrophic fuel vapor ignition due to lightning and its effects to be extremely improbable; and requires applicants to add airworthiness limitations to the airplane's Instructions for Continued Airworthiness (ICA) to prevent catastrophic fuel vapor ignition caused by lightning. These changes align the rule with the current understanding of lightning-related risk, fuel tank flammability exposure, and current airplane design practices. It also revises the title of § 25.981 to ''Fuel tank explosion prevention.''

This amendment removes lightning from the ignition sources regulated by § 25.981(a)(3). Inclusion of lightning in that section has resulted in applicants showing that compliance was impractical, leading them to seek exemptions to compliance with § 25.981 for fuel tank structure and systems. The FAA has granted several exemptions for fuel tank structure and systems. The FAA agrees, however, with the Large Airplane Fuel System Lightning Protection Aviation Rulemaking Committee (Lightning ARC) [4] that common regulatory treatment of structure- and systems-related lightning protection in the fuel system is appropriate. Applicants have also requested that the FAA develop special conditions to allow the consideration of fuel tank flammability and the probability of lightning strikes when meeting the requirement that a fuel tank explosion caused by lightning be extremely improbable. This amendment removes the necessity for such special conditions by incorporating such considerations into the rule.

To maintain the integrity of lightning protection features of airplanes, this amendment adds a new paragraph (d) to § 25.954 and amends part 25, appendix H, section H25.4(a) to require applicants to establish airworthiness limitations to protect the continued function of the lightning protection features of fuel tank structure and fuel systems.

This rule applies to applications for new type certificates, and applications for amended or supplemental type certificates on significant product-level change projects in which § 25.954, ''Fuel system lightning protection,'' is applicable to the changed area.

II. Background

A. Statement of the Problem

Section 25.954, adopted in 1967, required protection of the airplane from the effects of lightning, regardless of the likelihood that lightning would strike the airplane. The regulation did not acknowledge that lightning protection

[1] Fuel system, in the context of this final rule, includes any component within either the fuel tank structure or the fuel tank systems and any airplane structure or system components that penetrate, connect to, or are located within a fuel tank.

[2] Fuel tank structure, in the context of this final rule, includes structural members of the fuel tank such as airplane skins, access panels, joints, ribs, spars, stringers, and associated fasteners, brackets, coatings, and sealant.

[3] Fuel tank systems, or systems, in the context of this final rule, include tubing, components, and wiring that penetrate, connect to, or are located within a fuel tank.

[4] See the ''Large Airplane Fuel System Lightning Protection Rulemaking Recommendations'' report, May 2011, available in the docket.

features, or other features, could fail or become ineffective. The regulation also did not require evaluation of probabilities of failures affecting lightning protection features, nor did it require maintenance actions to ensure the continued effectiveness of design features that prevent catastrophic fuel vapor ignition.

Compliance with § 25.981(a)(3), at amendment 25–102,[5] required the assumption that lightning would strike the airplane (*i.e.,* that the probability of lightning was one) and that the design provide fail-safe ignition prevention means to preclude ignition sources from being present in fuel tanks when component failures, malfunctions, or lightning strikes occur. This typically resulted in the need for triple-redundant lightning ignition protection features because some structural failures may have long latency periods.[6] The FAA found, however, that for lightning protection, providing triple-redundant features is not always practical. This impracticality has led applicants to apply for exemptions and special conditions to ensure the design and maintenance actions provide for, and maintain, an acceptable level of safety. However, the processing and issuance of these exemptions and special conditions has created an administrative burden on industry and the FAA.

B. Related Actions

On May 26, 2009, the FAA issued a policy memorandum to standardize the process for granting exemptions and issuing special conditions for fuel tank structure lightning protection. FAA Policy Memorandum ANM–112–08–002, ''Policy on Issuance of Special Conditions and Exemptions Related to Lightning Protection of Fuel Tank Structure,'' defined alternative methods that could be applied through special conditions or exemptions to some areas of structural designs where compliance with § 25.981(a)(3) was impractical. This policy allowed the applicant's risk assessment to account for the reduced likelihood of the simultaneous occurrence of a critical lightning strike and a fuel tank being flammable. The policy explained the level of safety intended by § 25.981(a)(3) for fuel tank structure, and provided guidance for alternatives to compliance that still achieve that level of safety.

On June 24, 2014, the FAA superseded that policy memorandum with Policy Statement PS–ANM–25.981–02, ''Policy on Issuance of Special Conditions and Exemptions Related to Lightning Protection of Fuel Tank Structure and Systems,'' expanding the scope of the policy to include systems. The policy statement provided guidance for approval of special conditions and exemptions for lightning protection features in fuel tank structure and fuel systems with respect to § 25.981(a)(3).

The revisions to § 25.981(a)(3) in this amendment should eliminate the need to issue such special conditions and exemptions. However, some of the information in that policy statement will remain in Advisory Circular (AC) 25.981–1D, ''Fuel Tank Ignition Source Prevention Guidelines,'' [7] for this rule because the FAA expects that the information will continue to be useful in ensuring the level of safety required by the amended § 25.954 for fuel tank structure and systems.

The final rule will maintain the level of safety established by these policies. It codifies these policies into a performance-based rule that allows the applicant to choose the means of compliance.

C. Summary of the NPRM

On December 9, 2014, the FAA issued a notice of proposed rulemaking (NPRM) to amend §§ 25.954 and 25.981 and appendix H to part 25. The **Federal Register** published NPRM Notice No. 14–09, Docket No. FAA–2014–1027, on December 18, 2014. In the NPRM, the FAA proposed the following changes:

1. ''Fuel System Lightning Protection,'' (§ 25.954)

- Consolidate the requirements for the prevention of fuel vapor ignition due to lightning, currently in §§ 25.954 and 25.981, into § 25.954;
- Retain and renumber the existing rule text;
- Add lightning-induced or conducted electrical transients [8] to the lightning effects that applicants must consider;
- Add a new performance-based standard to require that a catastrophic fuel tank explosion be extremely improbable when taking into account the risk of failures, probability of a critical lightning strike, and fuel tank flammability exposure;
- Add maintenance requirements to maintain the integrity of lightning protection features during the airplane service life; and
- Define critical lightning strike and fuel system.

2. ''Fuel Tank Ignition Prevention,'' (§ 25.981)

- Remove the requirement to prevent lightning ignition sources and instead refer applicants to § 25.954 for lightning protection requirements;
- Clarify that the applicant must provide critical design control configuration limitations (CDCCLs) to identify critical design features in addition to inspections or other procedures; and
- Change the title to ''Fuel tank explosion prevention.''

3. ''Instructions for Continued Airworthiness,'' Appendix H to Part 25

- Add a new paragraph to make mandatory any inspection and test procedures that are needed to sustain the integrity of the lightning protection design features used to show compliance with § 25.954; and
- Add a new section to require applicants to develop ICA that protect the lightning protection features required by § 25.954.

The FAA proposed these changes based on recommendations from the Lightning ARC. The comment period closed on March 18, 2015.

III. Discussion of the Final Rule and Public Comments

The FAA received comments from eight (8) manufacturers and one (1) industry group. All of the commenters generally supported the proposed amendments. Some of the comments suggested changes.

In the discussion below, some comments identify paragraph designations of the rules as proposed in the NPRM. In this final rule, the FAA is revising and reorganizing some of those paragraphs, so paragraph references in the comments may be different from their designation in the final rule. This section references each paragraph according to its designation in this final rule, with the NPRM paragraph designation noted in brackets when there has been a change.

A. ''Fuel System Lightning Protection'' (§ 25.954)

With some differences from what the FAA proposed in the NPRM, this amendment requires that the design and installation of the airplane fuel system

[5] See 66 FR 23086 (May 7, 2001), ''Transport Airplane Fuel Tank System Design Review, Flammability Reduction, and Maintenance and Inspection Requirements.''

[6] In this context, latency period means the time interval between a failure and the discovery of that failure.

[7] AC 25.981–1D is available in the docket and on the internet at *http://www.faa.gov/regulations_policies/advisory_circulars/.*

[8] As used in this discussion, a transient is a brief electrical disturbance on wiring and equipment caused by the intense voltage, current, and electromagnetic fields associate with lightning.

prevent catastrophic fuel vapor ignition due to lightning and its effects. This final rule removes ''corona and streamering at fuel vent outlets'' as a lightning effect that applicants must consider, and adds ''lightning-induced or conducted electrical transients'' to the non-exclusive list of lightning effects against which the fuel system must be protected. This amendment adds definitions for ''critical lightning strike'' and ''fuel system'' to ensure common understanding and consistent application of those terms.

To comply with the revised § 25.954, this amendment requires applicants to show that catastrophic fuel vapor ignition is extremely improbable, taking into account flammability, critical lightning strikes, and failures within the fuel system.

To protect those features of the airplane that prevent catastrophic fuel vapor ignition due to lightning, this amendment adds a requirement that the type design include CDCCLs identifying those features and providing information to protect them. To ensure the continued effectiveness of those features, the rule requires that the type design specify necessary inspections and test procedures, intervals between repetitive inspections and tests, and mandatory replacement times. The rule also requires the applicant to include information regarding CDCCLs and methods for ensuring continued effectiveness of lightning protection features in the Airworthiness Limitations section (ALS) of the ICA.

The following is a discussion of comments the FAA received on the changes to § 25.954 as they were proposed in the NPRM.

1. Definitions

The NPRM proposed adding definitions of ''critical lightning strike'' and ''fuel system'' to § 25.954(d). This final rule revises these definitions and moves them to paragraph (a) of the section.

The AE–2 and WG–31 Lightning Committees (SAE Lightning Group) supported the proposed definition of ''fuel system.'' However, the FAA determined that the inclusion of the word ''other'' in the definition, ''A fuel system includes any component within either the fuel tank structure or the fuel tank systems, and any *other* airplane structure or system components that penetrate, connect to, or are located within a fuel tank,'' could be misinterpreted to exclude basic structure, such as wings, in the context of the definition. Therefore, the definition of fuel system in the final rule does not include ''other.''

The proposed definition of a ''critical lightning strike'' was ''. . . a lightning strike that attaches to the airplane in a location that affects a failed feature or a structural failure, and the amplitude of the strike is sufficient to create an ignition source when combined with that failure.'' The SAE Lightning Group requested changes to this definition for clarity. The commenter requested that the term ''failed feature'' be changed to ''failed protection feature,'' but did not provide a rationale. The commenter also stated that it is unnecessary to list structural failures separately. The commenter further stated that the inclusion of ''a failed [protection] feature'' already includes structural failures, which otherwise could result in an ignition source. The commenter also suggested revising the definition to, ''A critical lightning strike is a lightning strike that attaches to the airplane in a location that affects a failed protection feature with characteristics that could create an ignition source when combined with that failure.''

The FAA partially agrees with the SAE Lightning Group's requests. The FAA modified the definition of critical lightning strike by deleting ''the amplitude of the strike is sufficient,'' but did not replace that text with ''characteristics that could,'' as the commenter recommended. The definition is clear without either of those phrases. The FAA also did not replace ''failed feature'' with ''failed protection feature,'' or delete the phrase ''structural failure.'' To address the comments, we have revised the definition by removing the phrase ''failed feature'' and stating instead that, ''A critical lightning strike is a lightning strike that attaches to the airplane in a location that, when combined with the failure of any design feature or structure, could create an ignition source.''

In this revised definition, a ''design feature'' means any feature specifically designed for lightning protection or any other design feature whose failure, when combined with a lightning strike, could cause ignition. An example of a design feature that is specifically designed for lightning protection is a metal foil layer installed between the laminate layers of a composite wing. An example of a design feature that is not specifically designed for lightning protection but whose failure, when combined with a lightning strike, could cause ignition is a swaged fitting on a hydraulic tube located within the fuel tank. Structural failures that could create an ignition source in the event of a lightning strike must also be addressed and, therefore, the final definition includes ''any design feature or structure.''

Related to the definition of critical lightning strike, the NPRM stated that a critical lightning strike occurs ''on the order of once every 100,000 hours of airplane operation.'' The SAE Lightning Group commented that the location of the lightning's attachment to the airplane, whether the strike's amplitude is sufficient to create an ignition source, and the effect of a failed feature or structural failure are all design-dependent. The SAE Lightning Group also commented that compliance with § 25.954 would require use of a strike rate of 1 in 100,000 hours. The commenter suggested that the FAA should allow applicants to identify how often a critical lightning strike might occur relative to their designs.

The intent of the statement in the NPRM that a critical lightning strike occurs once per 100,000 hours was to provide a general understanding of their average rate of occurrence. It was not intended as a rate to be used in demonstrating compliance. The FAA agrees with the SAE Lightning Group that the actual rate of a critical strike would be based on an applicant's analysis of the specific airplane design features, which include additional factors such as location of the strike, characteristics of the lightning strike, failure of design features and structure, and specific ignition source thresholds for each feature failure and failure mode.

Related to this same discussion in the NPRM, Parker Aerospace (''Parker'') requested that the FAA add a paragraph to § 25.954 that describes all of the conditions and guidance regarding probabilities that the applicant must consider, such as flammability exposure and failure latency of inerting systems. The FAA disagrees with Parker's request. Rather than make such conditions and guidance on probabilities mandatory via a new paragraph in § 25.954, such guidance is included in AC 25.954–1, ''Transport Airplane Fuel System Lightning Protection.'' [9] The AC discusses the probability for different airplane composite tank structures and threat levels.

2. Relationship of § 25.954 to §§ 25.901 and 25.1309

The SAE Lightning Group suggested that the FAA clearly state that the revised § 25.954 takes precedence over the general requirements of §§ 25.901,

[9] AC 25.954–1 is available in the docket and on the internet at *http://www.faa.gov/regulations_policies/advisory_circulars/.*

''Installation'' (''Subpart E—Powerplant''), and 25.1309, ''Equipment, systems, and installations.'' The FAA disagrees. Section 25.954 does not supersede the requirements of § 25.901 or § 25.1309. However, compliance with § 25.954 may assist applicants in showing compliance with other regulations.

3. Lightning Effects

The NPRM proposed adding ''lightning-induced or conducted electrical transients'' to the lightning effects in § 25.954(b) [paragraph (a) in the NPRM] that applicants must ensure will not cause ignition of fuel vapor within the fuel system. The SAE Lightning Group recommended that, rather than adding to the existing list of lightning threats in the rule, the FAA delete the list of lightning effects. Instead, the SAE Lightning Group recommended that the rule include a more general and inclusive reference to lightning that requires that the airplane be protected against catastrophic effects from lightning. The SAE Lightning Group suggested that the list may not be complete and may be inconsistent with lightning environments defined in the industry documents accepted by the FAA in AC 20–155A, ''Industry Documents to Support Aircraft Lightning Protection Certification.'' In contrast, Parker supported keeping the text as proposed, including ''lightning-induced or conducted electrical transients.''

The FAA disagrees with the SAE Lightning Group's suggestion to include only a general lightning requirement. Relying on guidance material to detail the lightning effects that applicants must consider could result in some applicants not addressing all effects. However, the FAA recognizes that the list of effects, as proposed, could be misinterpreted as an exhaustive list. Therefore, the FAA added ''including'' to the text that introduces the list to clarify that the list is not exhaustive. The FAA agrees to limit, in § 25.954(b), the type of fuel vapor ignition that must be prevented to ''catastrophic'' events. This change will make the requirement consistent with Policy Statement PS–ANM–25.981–02, which states that ''the fuel tank structure and systems must be designed and installed to prevent catastrophic fuel vapor ignition due to lightning.'' This change also makes § 25.954(b) consistent with § 25.581, which requires that the airplane be protected against ''catastrophic'' effects from lightning. Thus, § 25.954(b) now states, ''The design and installation of a fuel system must prevent catastrophic fuel vapor ignition due to lightning and its effects, including . . . .''

The SAE Lightning Group recommended the removal of ''corona and streamering at fuel vent outlets'' from the list of lightning effects because that term is inconsistent with the terminology in the industry guidance material recommended by AC 20–155A. The FAA agrees and has removed this term from the final rule.

4. Fault-Tolerant Design

Regarding § 25.954(c) [paragraph (b) in the NPRM], the SAE Lightning Group requested that the FAA require that catastrophic fuel vapor ignition due to lightning be prevented by demonstrating that the fuel system ignition source protection design is fault tolerant, or for designs that are not fault tolerant, by showing catastrophic fuel vapor ignition to be extremely improbable, taking into account flammability, critical lightning strikes, and failures in the fuel system. The SAE Lightning Group argued that the proposed broader requirement to show that catastrophic ignition is extremely improbable, without requiring a fault tolerant design, would be costly and would negate the savings to industry stated in the regulatory evaluation. In a related comment, Bombardier S.A. (Bombardier) requested that ''fault tolerant'' be defined to clarify if it is equivalent to single fault tolerance and the type of compliance that the FAA would expect, numerical analysis or qualitative. Although the term was not used in the proposed rule (and is not in the final rule), Bombardier suggested more clarity was needed in the rule and supporting guidance.

The FAA agrees that fuel systems designed with reliable fault-tolerant ignition source protection features should comply with the requirement that catastrophic fuel vapor ignition be extremely improbable. As used in this context, a fault-tolerant fuel system design is a design that precludes ignition sources in the fuel system even when a fault is present; ''reliable'' means the ability to maintain the effectiveness of the protection features over the service life of the individual airplane.

However, the FAA disagrees that fault tolerance should be required because fault tolerance is only one possible means of compliance with the requirement that catastrophic fuel vapor ignition be extremely improbable. The use of a full-time flammability control system (*e.g.,* fuel system inerting) exceeding the current part 25 flammability reduction means (FRM) performance standard could be another means of compliance. If the FAA limited the requirement to fault tolerance as requested by the SAE Lightning Group, such a design approach, or others as technology progresses, would not be allowed.

Regardless of the design approach chosen by the applicant to prevent lightning-induced catastrophic fuel vapor ignition, a safety analysis will be necessary to demonstrate extreme improbability. The complexity of the analysis can range from a relatively simple assessment to establish any maintenance requirements for reliable fault-tolerant ignition protection features, to a more in-depth analysis if non-fault-tolerant design features are used. For reliable fault-tolerant features, this analysis would be substantially less costly than traditional methods for showing that catastrophic failures are extremely improbable. The supporting AC 25.954–1 provides guidance on methods for both fault-tolerant and FRM compliance approaches, including the necessary safety assessment, which could be numerical, qualitative, or a combination of the two.

The FAA disagrees with Bombardier's request to define fault-tolerant in § 25.954. Since a fault-tolerant design is not a requirement for compliance with this rule, there is no need to provide a regulatory definition. However, the supporting AC 25.954–1 includes the definition for fault-tolerant design noted earlier in this section (4. Fault-Tolerant Design), ''A fault-tolerant fuel system design is a design that precludes ignition sources in the fuel system even when a fault is present.''

Therefore, this amendment retains the requirement in § 25.954(c) that catastrophic fuel vapor ignition be extremely improbable, and clarifies its relationship with paragraph (b). The revised § 25.954(c) states, ''To comply with paragraph (b) of this section, catastrophic fuel vapor ignition must be extremely improbable, taking into account flammability, critical lightning strikes, and failures within the fuel system.''

The SAE Lightning Group also commented that the FAA should revise the regulatory evaluation if the FAA does not adopt the SAE Lightning Group's recommendation to replace the requirement of extreme improbability with fault tolerance. The commenter argued that the requirement to show that fuel tank ignition is extremely improbable would be costly and negate the savings to industry shown in the regulatory evaluation. The SAE Lightning Group did not submit any supporting financial data.

The FAA does not agree that the requirement to show that fuel tank

ignition is extremely improbable would be costly and negate the savings to industry. In general, an applicant that can show its design is reliably fault-tolerant will not need to conduct an extensive safety analysis. The requirement to develop airworthiness limitations for critical lightning protection features will result in the need for the applicant to assess the reliability of the features and provide appropriate maintenance tasks to achieve an acceptable level of reliability.

In addition, this rule allows both fault-tolerant and non-fault-tolerant design approaches. Under the rule, the fuel system must prevent catastrophic fuel vapor ignition due to lightning. To comply with this requirement, catastrophic fuel vapor ignition must be extremely improbable. If an applicant's design achieves this requirement through the use of fault-tolerant design, the safety analysis (§ 25.1309) to support the design will not have to be as extensive as one that would be necessary to support a non-fault-tolerant design. As a result, the rule allows industry the flexibility to select the means of compliance based on design approach, safety analysis, and costs. Therefore, the FAA determined that the regulatory evaluation did not need to be revised as a result of this comment.

5. Flammability Reduction Means (FRM) as a Means of Compliance

The SAE Lightning Group, Bombardier, and Parker all commented on the discussion of fuel tank flammability reduction in the NPRM and asked for clarification of how flammability reduction could be used as a means of compliance with § 25.954.

Boeing stated that the majority of the NPRM discussion of fuel tank FRM was unnecessary because applicants could infer that the FAA would relax the requirement for providing fault tolerance if the FAA allowed FRM as a sole means of compliance. Boeing did not agree that the FAA should accept controlling fuel tank flammability as the primary means for preventing a fuel tank explosion without providing fault-tolerant lightning protection features.

As discussed in the previous section (4. Fault-Tolerant Design), the FAA does not agree that the lightning protection requirement in § 25.954 should dictate the use of fault-tolerant ignition protection features in the design without allowing the use of flammability control means. As explained in the NPRM, the intent of the amendment to § 25.954 is to require the design to take into account the likelihood of a critical lightning strike, the fuel tank being flammable, and the creation of an ignition source due to the failure of fuel system or structural lightning protection features. If designers develop a full-time fuel tank flammability control system that prevents the fuel tanks from being flammable during all foreseeable operating conditions and all phases of airplane operation (including descent), resulting in the probability of a fuel tank explosion being extremely improbable, this could achieve the level of safety that § 25.954 requires, and could be used as a means of compliance without the need for fault-tolerant lightning protection features. While fuel tank flammability control system technology has not evolved to a state where flammability control can replace the need for fault-tolerant ignition prevention, the FAA's goal is to develop rules that are performance-based, and in this case, to allow designers to comply via the use of flammability control when the technology is adequately developed. Allowing the use of fuel tank FRM for demonstrating compliance with the rule could offer designers the opportunity to reduce the number of fault-tolerant features and mandatory maintenance actions.

6. CDCCLs

Section 25.954(d) [paragraph (c) in the NPRM] requires that the type design include CDCCLs identifying those design features that prevent catastrophic fuel vapor ignition caused by lightning and providing information to protect them. To ensure the continued effectiveness of those features, paragraph (d) also requires that the type design include inspections and test procedures, intervals between repetitive inspections and tests, and mandatory replacement times. This paragraph also requires applicants to place all this information in the ALS of the ICA.

The SAE Lightning Group proposed that CDCCLs be included as cautions [10] in the airplane maintenance manual, not as airworthiness limitations in the ALS of the ICA. The SAE Lightning Group suggested that, as proposed, the requirement would create a burden on the airlines because the ALS documents are not used by the airline mechanics, and therefore the CDCCL information must be duplicated and links created for the information in both the ALS documents and the maintenance documents used by the mechanics. The commenter stated that if the FAA does not agree with this approach, then only critical information necessary to demonstrate compliance, along with CDCCLs, should be included as airworthiness limitations, and proposed that the regulatory text be amended to reflect this request. The SAE Lightning Group did not define what it considered critical information.

The FAA disagrees with the SAE Lightning Group's request to move the CDCCLs from the ALS of the ICA to the Cautions section of the maintenance manual. CDCCLs provide information that is essential for protecting the design features that are critical for preventing fuel tank explosions. The Caution section of the maintenance manual is not mandatory for U.S. operators, and therefore CDCCLs need to be included in the ALS of the ICA, which is mandatory.

The SAE Lightning Group commented that, since the Lightning ARC study and report in 2011, the use of Air Transport Association (ATA) Maintenance Steering Group (MSG)–3 [11] processes has not been effective in establishing maintenance requirements for lightning protection features and does not take into consideration the many factors that are critical for certification. This can create conflicting or duplicate fuel tank entry requirements. To eliminate this potential duplication, the SAE Lightning Group stated that industry now recommends that maintenance practices for both fault-tolerant and non-fault-tolerant protection features be established via the type certification process only, and that the ATA MSG–3 process should not be used for this purpose.

Airbus and Airlines for America disagreed with the request to establish maintenance practices for both fault-tolerant and non-fault-tolerant protection features via the type certification process. Both commenters proposed that the FAA require airworthiness limitations and CDCCLs for only non-fault-tolerant design features. Both commenters stated that an airworthiness limitation requirement for fault-tolerant design features could be a disincentive to develop fault-tolerant designs and may increase the burden on operators unnecessarily. As an alternative, they proposed reliance on the current ATA MSG–3 process for establishing maintenance programs for

[10] Cautions in an airplane maintenance manual call attention to methods and procedures that must be followed to avoid damage to equipment (ATA iSpec 2200, *Information Standards for Aviation Maintenance,* published by Airlines for America, 2014).

[11] ATA MSG–3 is a maintenance steering group composed of regulatory authorities, operators, and manufacturers that, through a process, develop documents that present a methodology for developing scheduled maintenance tasks and intervals for aircraft structure, systems, and components.

fault-tolerant design features. Airbus also suggested that operational rules and guidance could be established to prevent tasks identified through the ATA MSG–3 process from being deleted in service.

The FAA agrees with the SAE Lightning Group that all maintenance practices for both fault-tolerant and non-fault-tolerant protection features be established via the type certification process and not through the ATA MSG–3 process. Using the certification process will ensure that applicants develop necessary maintenance actions to maintain the integrity of lightning ignition source protection features. As all maintenance actions necessary to ensure the integrity of lightning ignition source protection features will be addressed by compliance with section H25.4(a)(5), the ICA requirement in the proposed section H25.X is not necessary and has been deleted from the final rule. This is discussed further in the discussion regarding appendix H.

The FAA disagrees with Airbus' and Airlines for America's proposal to rely on the ATA MSG–3 process for development of maintenance actions for fault-tolerant design features. U.S. operators are not required to adopt the ATA MSG–3 developed maintenance program, but they are required to include all airworthiness limitations in their maintenance program.[12] Therefore, airworthiness limitations are needed to ensure an operator's maintenance program includes all tasks determined by the safety analysis, performed as part of the system's certification activity, to be critical. The safety analysis may show that some fault-tolerant features are life-limited or require periodic inspection, so mandatory maintenance tasks established through engineering review and approval would be needed. Therefore, the FAA did not change this rule as a result of these comments.

The SAE Lightning Group also stated that the reference to § 25.1729 in § 25.954(d) is not within the scope of this rule and requested that it be removed. The FAA agrees and removed that reference from the final rule.

Embraer suggested that § 25.954(d) include the same requirement that is in § 25.981(d). Section 25.981(d) requires the type design to include visible means for identifying critical features in areas where foreseeable maintenance actions, repairs, or alterations may compromise the CDCCLs. Embraer stated that this would harmonize both requirements.

The FAA does not agree. Because of the large number and multiple types of bonding features used for fuel tank and system lightning protection, it is not practical to require installation of visible means of identification for all lightning-related CDCCLs. However, all critical lightning protection features identified as CDCCLs must be included in the ALS of the ICA. Although the FAA made minor editorial changes [13] to the final § 25.954(d), the requirement that the type design include CDCCLs is adopted as proposed.

B. ''Fuel Tank Explosion Protection'' (§ 25.981)

Section 25.981 requires that the airplane design protect the fuel tank and fuel tank system against ignition from all sources. This amendment adds an exception to § 25.981(a)(3) to remove lightning as an ignition source from the scope of this section and refers applicants to § 25.954 for lightning protection requirements.

Paragraph (d) of § 25.981 requires applicants to establish CDCCLs, inspections, or other procedures to ensure fuel tank safety. This amendment revises paragraph (d) to clarify that applicants must provide CDCCLs to identify critical design features, in addition to inspections or other procedures. The FAA received the following comments on the proposed changes to this section.

1. Consistency of Language

Boeing suggested that the FAA expand the applicability of § 25.981(d) to include the fuel tank system, in addition to the fuel tank, to be consistent with § 25.981(a). Paragraph (a) of § 25.981 requires ignition source prevention in the ''fuel tank or fuel tank system.''

The FAA agrees and revised the final rule to add, ''. . . or fuel tank system according to paragraph (a) of this section. . . .'' This addition makes it consistent with § 25.981(a).

Boeing proposed that § 25.981(d) refer to paragraph (b) of that section in addition to the references to paragraphs (a) and (c) of that section because mandatory maintenance required by paragraph (d) should also apply to flammability reduction means.

The FAA agrees, and this amendment includes a reference to paragraph (b) in § 25.981(d).

2. CDCCL Visible Means

Boeing requested that the FAA revise § 25.981(d) to delete the requirement for placement of visible means, limit that placement to areas where the means would be ''practical and meaningful,'' or provide more clear guidance. Boeing stated that, as proposed, the regulation provides no practical way to fully comply with the requirement to provide visible means of identifying CDCCL. Boeing argued that, ''While it may be easy to pick the color of external fuel quantity wiring, much of the fuel tank design for ignition prevention is basic to airplane design, such as bonding, grounding, sealing, etc. There is no practical way to color code or otherwise identify these design features.''

The FAA partially agrees. The intent is not to require markings in all locations—only in those locations where foreseeable errors due to maintenance actions, repairs, or alterations may compromise critical features. This is not a new requirement with this amendment. However, this amendment deletes the example of visible means (color coding of wire to identify separation limitation), and it removes the requirement of identifying visible means as CDCCLs, both of which had been added at amendment 25–125. AC 25.981–1D provides additional guidance.

C. ''Instructions for Continued Airworthiness'' (Appendix H to Part 25)

With some differences from what the FAA proposed in the NPRM, this amendment adds a new paragraph, (a)(5), to section H25.4 of appendix H to part 25. This paragraph requires any mandatory replacement times, inspection intervals, related inspection and test procedures, and CDCCLs for lightning protection features approved under § 25.954 to be included in the ALS of the ICA.

The SAE Lightning Group proposed revisions to the airworthiness limitation requirements of section H25.4(a)(5) by adding the phrases ''critical design configuration control limitations'' and ''fault tolerant and non-fault tolerant.'' The commenter stated that the revisions would align this paragraph with the SAE Lightning Group's requested changes to § 25.954 regarding fault-tolerant and non-fault tolerant designs. The commenter also requested deletion of the proposed section H25.X, stating that the MSG–3 process has been shown to be ineffective for maintenance inspections and procedures that are critical to fuel tank systems lightning protection.

[12] Section H25.4(a) and 14 CFR 91.403(c).

[13] The FAA deleted ''on how'' in the first sentence of the paragraph, ''. . . (CDCCLs) identifying those features and providing information *on how* to protect them,'' and added ''used in demonstrating compliance to paragraph (b) of this section'' in the second sentence, ''. . . and mandatory replacement times for those design features *used in demonstrating compliance to paragraph (b) of this section*.''

Although Airbus was a participant in the SAE Lightning Group, it disagreed with the above comments on section H25.4(a)(5) because it makes reference to the ALS as being the only means to develop the ICA for both fault-tolerant and non-fault tolerant lightning protection features. Airbus suggested instead that the FAA limit the applicability of section H25.4(a)(5) to non-fault-tolerant lightning protection features rather than to all lightning protection features. Airbus also asked that the FAA delete the reference to sampling programs in section H25.X. Airbus stated that sampling programs are typically managed by the type certificate applicant, not the operator of the airplane that uses the ICA to develop their maintenance programs.

The FAA partially agrees with the SAE Lightning Group's proposed changes. The FAA does not agree to the proposed changes to section H25.4(a)(5) as the FAA did not adopt the SAE Lightning Group's requested changes to § 25.954, with the exception of deleting reference to § 25.1729. However, the FAA did add the term ''critical design configuration control limitations'' to the final section H25.4(a)(5). Thus, section H25.4(a)(5) now states, ''Each mandatory replacement time, inspection interval, and related inspection and test procedure, and each critical design configuration control limitation for each lightning protection feature approved under § 25.954.''

The FAA agrees with the request to delete the proposed new section H25.X because all necessary maintenance actions for ensuring the integrity of lightning ignition source protection features will be addressed by compliance with section H25.4(a)(5). Therefore, the ICA requirement in the proposed section H25.X is not necessary, so that section is not included in the final rule. This also addresses Airbus's request to delete the reference to sampling programs in section H25.X. The FAA disagrees with Airbus's request to add the phrase ''non-fault-tolerant'' to section H25.4(a)(5) because all necessary maintenance actions, both fault-tolerant and non-fault-tolerant, must be included in the ALS as required by section H25.4(a)(5).

D. Miscellaneous Comments

1. Hazards of Electrostatic Charge

An individual suggested that the FAA revise §§ 25.954 and 25.981 to include a requirement for fuel system design features to mitigate the hazards of electrostatic charge. The commenter stated that these design features would also have a role in lightning protection.

Section 25.899 specifically addresses electrostatic charge, and § 25.981 addresses all ignition sources, which would include electrostatic charge. Lightning is the only exception, and it is now addressed by § 25.954. Adding a specific requirement for electrostatic charge to §§ 25.954 and 25.981 would be redundant and may cause confusion. Therefore, the FAA did not revise the rules because of this comment.

2. Regulatory Evaluation

Boeing requested that the FAA explain the assumption made in paragraph IV.A.3 of the NPRM preamble, ''Regulatory Notices and Analyses, Regulatory Evaluation, Assumptions and Data Sources,'' that computational weights of composite wing airplanes would change from current approximate 15%–25% level linearly increasing to 50% level for a ten-year production cycle.

The FAA clarified the information with the major manufacturer that had provided the data during the development of the NPRM regulatory evaluation. The assumption is more correctly stated that the weighted production rate of composite wing airplanes is estimated at 15%–25% of total production at the beginning of the 10-year production cycle, increasing linearly to 50% at the end of the cycle.

IV. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule. We suggest readers seeking greater detail read the full regulatory evaluation, a copy of which we have placed in the docket for this rulemaking.

In conducting these analyses, FAA has determined that this final rule: (1) Has benefits that justify its costs; (2) is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866; (3) is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (4) will not have a significant economic impact on a substantial number of small entities; (5) will not create unnecessary obstacles to the foreign commerce of the United States; and (6) will not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

1. Total Benefits and Costs of This Rule

This final rule will be relieving for both government and industries with the estimated net benefits. The FAA assesses cost savings based on resources saved for reducing regulatory burden on both industry and the FAA. This rule results in cost savings by reducing the number of exemptions and special conditions.

Over a 10-year period, the average total present value savings to manufacturers and the FAA are about $29.03 million at a 7% discount rate with annualized savings of about $4.13 million. The lower and the higher estimates of the total present value savings are $16.17 million and $41.93 million at a 7% discount rate, with annualized savings of $2.30 million and $5.97 million, respectively. The final rule will maintain achieved safety levels related to fuel tank structure and system lightning protection commensurate with the current requirements.

Parties Potentially Affected by this Rulemaking will be:

- Part 25 airplane manufacturers.
- Operators of part 25 airplanes.
- The Federal Aviation Administration.

Assumptions and Data Sources.

- Data related to industry savings mainly come from airplane manufacturers.
- Data related to requests for exemptions and special conditions come from FAA internal data sources and the judgments of agency subject matter experts.

- The FAA would process 4 special conditions and 7 exemptions in the next 10 years in the absence of this rule.[14]
- Domestic airplane manufacturers would petition for two special conditions and three exemptions before reaching their cost-benefit steady-state.[15]
- While foreign manufacturers may benefit also from this final rule, cost savings directly attributable to foreign entities are not included in this analysis.
- For the final rule, the FAA estimates cost savings from avoided petitions for exemption and special conditions occur at the beginning of a 10-year production cycle.
- Projected impacts on manufacturers and the government are for a 10-year period associated with one production cycle.
- All monetary values are expressed in 2016 dollars.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule amends certain airworthiness regulations that were not always practical for transport category airplanes regarding lightning protection of fuel tanks and systems. This final rule provides burden relief and savings to airplane manufacturers, who are large entities. Therefore, as provided in section 605(b), the head of the FAA certifies that this final rule will not have a significant economic impact on a substantial number of small entities and also certifies that a regulatory flexibility analysis is not required. The FAA solicited comments in the NPRM and did not receive comments with regard to this certification. Therefore, the FAA Administrator certifies that this rule does not have a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and determined that it could result in the same benefits to domestic and international entities in accord with the Trade Agreements Act.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this final rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a ''significant energy action'' under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

[14] FAA internal data source and the judgment of agency subject matter experts.

[15] See footnote 14.

C. Executive Order 13609, International Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

D. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This final rule is considered an E.O. 13771 deregulatory action. Details on the estimated cost savings of this rule can be found in the rule's economic analysis.

VI. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained from the internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);
2. Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies/;* or
3. Accessing the Government Printing Office's web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9680.

B. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

■ 1. The authority citation for part 25 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702 and 44704.

■ 2. Revise § 25.954 to read as follows:

§ 25.954 Fuel system lightning protection.

(a) For purposes of this section—

(1) A critical lightning strike is a lightning strike that attaches to the airplane in a location that, when combined with the failure of any design feature or structure, could create an ignition source.

(2) A fuel system includes any component within either the fuel tank structure or the fuel tank systems, and any airplane structure or system components that penetrate, connect to, or are located within a fuel tank.

(b) The design and installation of a fuel system must prevent catastrophic fuel vapor ignition due to lightning and its effects, including:

(1) Direct lightning strikes to areas having a high probability of stroke attachment;

(2) Swept lightning strokes to areas where swept strokes are highly probable; and

(3) Lightning-induced or conducted electrical transients.

(c) To comply with paragraph (b) of this section, catastrophic fuel vapor ignition must be extremely improbable, taking into account flammability, critical lightning strikes, and failures within the fuel system.

(d) To protect design features that prevent catastrophic fuel vapor ignition caused by lightning, the type design must include critical design configuration control limitations (CDCCLs) identifying those features and providing information to protect them. To ensure the continued effectiveness of those design features, the type design must also include inspection and test procedures, intervals between repetitive inspections and tests, and mandatory replacement times for those design features used in demonstrating compliance to paragraph (b) of this section. The applicant must include the information required by this paragraph in the Airworthiness Limitations section of the Instructions for Continued Airworthiness required by § 25.1529.

■ 3. Amend § 25.981 by revising the section heading and paragraphs (a)(3) and (d) to read as follows:

§ 25.981 Fuel tank explosion prevention.

(a) * * *

(3) Except for ignition sources due to lightning addressed by § 25.954, demonstrating that an ignition source could not result from each single failure, from each single failure in combination with each latent failure condition not shown to be extremely remote, and from all combinations of failures not shown to be extremely improbable, taking into account the effects of manufacturing variability, aging, wear, corrosion, and likely damage.

* * * * *

(d) To protect design features that prevent catastrophic ignition sources within the fuel tank or fuel tank system according to paragraph (a) of this section, and to prevent increasing the flammability exposure of the tanks above that permitted in paragraph (b) of this section, the type design must include critical design configuration control limitations (CDCCLs) identifying those features and providing instructions on how to protect them. To ensure the continued effectiveness of those features, and prevent degradation of the performance and reliability of any means provided according to paragraphs (a), (b), or (c) of this section, the type design must also include necessary inspection and test procedures, intervals between repetitive inspections and tests, and mandatory replacement times for those features. The applicant must include information required by this paragraph in the Airworthiness Limitations section of the Instructions for Continued Airworthiness required by § 25.1529. The type design must also include visible means of identifying critical features of the design in areas of the airplane where foreseeable maintenance actions, repairs, or alterations may compromise the CDCCLs.

■ 4. In appendix H to part 25, section H25.4, add new paragraph (a)(5) to read as follows:

Appendix H to Part 25—Instructions for Continued Airworthiness

* * * * *

H25.4 Airworthiness Limitations section.

(a) * * *

(5) Each mandatory replacement time, inspection interval, and related inspection and test procedure, and each critical design configuration control limitation for each lightning protection feature approved under § 25.954.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on September 6, 2018.

Carl Burleson,

Acting Deputy Administrator.

[FR Doc. 2018–20174 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2017–F–3717]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulation for vitamin D_3 to replace the current Reference Daily Intake (RDI) percentage values of calcium in 100 percent fruit juices and fruit juice drinks with absolute values and to update the reference for vitamin D_3 specifications. We are taking this action in response to a food additive petition filed by the Juice Products Association.

DATES: This rule is effective September 20, 2018. Submit either electronic or written objections and requests for a hearing on the final rule by October 22, 2018. The Director of the Federal Register approves the incorporation by reference of certain publications listed in the rule as of September 20, 2018. See the **ADDRESSES** section and the OBJECTIONS section IX of this document for further information on filing objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before October 22, 2018. The *https://www.regulations.gov* electronic filing system will accept objections until midnight Eastern Time at the end of October 22, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2017–F–3717 for ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3 Final Rule.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 26, 2017 (82 FR 34615), amended August 22, 2017 (82 FR 39711), we announced that we filed a food additive petition (FAP 7A4818) submitted on behalf of the Juice Products Association by Hogan

Lovells US LLP, Columbia Square, 555 Thirteenth Street NW, Washington, DC 20004. The petition proposed to amend the food additive regulations in § 172.380 (21 CFR 172.380), *Vitamin D_3*, to replace the currently specified minimum RDI percentage values of calcium in calcium-fortified 100 percent fruit juices and fruit juice drinks with absolute values. Specifically, § 172.380(c)(1) currently provides for the use of vitamin D_3 at a level not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices that are fortified with greater than or equal to 33 percent of the RDI of calcium per 240 mL, excluding fruit juices that are specifically formulated or processed for infants. In addition, § 172.380(c)(2) provides for the use of up to 100 IU of vitamin D_3 per 240 mL in fruit juice drinks that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL, excluding fruit juice drinks that are specifically formulated or processed for infants. The petitioner proposed to replace the RDI percentage values of calcium in 100 percent fruit juices and fruit juice drinks in these regulations with the absolute values of added calcium of 330 milligrams (mg) and 100 mg per 240 mL, respectively. The petitioner also requested that we update the reference for specifications for vitamin D_3 in § 172.380(b) from the 9th edition of the Food Chemicals Codex (FCC 9) to the 10th edition (FCC 10).

II. Evaluation of Petition

Section 409(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(i)) states that we shall, by regulation, establish the procedure for amending or repealing a food additive regulation, and that this procedure shall conform to the procedure provided in section 409 of the FD&C Act. Our regulations specific to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive (§ 171.130(a) (21 CFR 171.130(a))). The regulations further provide that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data submitted as a food additive petition must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting such petitions (§ 171.130(b)).

In the **Federal Register** of February 27, 2003 (68 FR 9000), we issued the regulations at § 172.380(c)(1) and (2) permitting the use of vitamin D_3 in calcium fortified 100 percent fruit juices and fruit juice drinks. We took that action in response to a food additive petition (FAP 2A4734) from the Minute Maid Co. (Minute Maid). Minute Maid petitioned for vitamin D_3 to be allowed to be added to calcium-fortified 100 percent fruit juices and fruit juice drinks so that the calcium and vitamin D levels are comparable to the levels in milk. When we issued these regulations in 2003, the RDI for calcium was 1,000 mg; however, in the **Federal Register** of May 27, 2016 (81 FR 33742), we issued a final rule which, among other things, redefined the RDI of calcium for adults and children 4 years of age and older to 1,300 mg (21 CFR 101.9(c)(8)(iv)). Because of the change in the RDI for calcium, the minimum level of added calcium in 100 percent fruit juice that may be fortified with vitamin D_3 increased from 330 mg to 430 mg and in fruit juice drinks from 100 mg to 130 mg.

The Juice Products Association stated that the proposed revision of § 172.380 to specify absolute values of calcium on a mg/mL basis rather than a percentage of RDI is needed to maintain the relative parity between fortified 100 percent fruit juices and fruit juice drinks and many dairy products. Without this change, the petitioner stated that 100 percent fruit juices with vitamin D_3 would have higher calcium levels than milk. The petitioner also stated that the higher levels of calcium resulting from the redefined RDI for calcium present formulation challenges and may adversely impact the taste of the juice or juice drink, which could deter consumers from selecting calcium and vitamin D fortified juices. Therefore, the petitioner proposed that § 172.380 be amended to express the allowable added calcium levels on a mg basis consistent with the calcium levels before the revision of the RDI for calcium. In doing so, the allowable levels of calcium and vitamin D in 100 percent fruit juices and juice drinks would again be comparable to the levels in milk.

Because the petitioner sought to revise the existing regulation to restore the amount of calcium fortification required to levels on par with milk, without introducing new uses for vitamin D_3 or changing the levels of vitamin D_3 and calcium that were considered when the regulations were established, there is no increase in dietary exposure to vitamin D_3 or to calcium. Therefore, we have determined that there are no safety concerns as a result of the proposed amendment.

Additionally, the current regulation for the use of vitamin D_3 in food (§ 172.380) indicates that the additive must meet the specifications in the 9th edition of the Food Chemicals Codex (FCC 9). The petitioner requested that we update the specifications for vitamin D_3 in § 172.380 by replacing the existing FCC 9 reference with the 10th edition of the Food Chemicals Codex (FCC 10), the most recent edition at the time the petition was submitted. The specifications for vitamin D_3 in FCC 10 are identical to those in FCC 9. However, since we received the petition, FCC has been updated to the 11th edition (FCC 11). The specifications for vitamin D_3 in FCC 11 are identical to those in FCC 10. Therefore, we are amending § 172.380 by adopting the specifications for vitamin D_3 in FCC 11 in place of FCC 9, because FCC 11 is the most current version.

III. Incorporation by Reference

FDA is incorporating by reference the monograph from Food Chemicals Codex, 11th ed., 2018, pp. 1243–1244 (vitamin D_3), which is approved by the Director of the Office of the Federal Register. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852, 1–800–227–8772, *http://www.usp.org/.* Copies also may be examined at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039.

The FCC monograph establishes the standard for purity and identity for vitamin D_3. The monograph provides specifications and analytical methodologies used to identify the substance and establish acceptable purity criteria. To ensure that only food grade vitamin D_3 is used in foods listed in § 172.380, the additive must meet the specifications and identity in the FCC monograph.

IV. Conclusion

Based on data and information in the petition, we conclude that amending the food additive regulations in the regulation for vitamin D_3 to replace the current RDI percentage values of calcium in 100 percent fruit juices and fruit juice drinks with absolute values is safe and appropriate. Thus, the RDI percentage values of calcium in 100 percent fruit juices and fruit juice drinks in these regulations are replaced with the absolute values of added calcium of

330 mg and 100 mg per 240 mL, respectively. Consequently, we are amending the food additive regulations as set forth in this document.

Additionally, the current regulation for the use of vitamin D_3 in food (§ 172.380) indicates that the additive must meet the specifications in FCC 9. The more current version is FCC 11, which contains specifications for vitamin D_3 that are identical to those in FCC 9. We are amending § 172.380 by adopting the specifications for vitamin D_3 in FCC 11 in place of FCC 9.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the July 26, 2017, **Federal Register** notice of filing (82 FR 34615). We stated in the notice of filing that we had determined, under 21 CFR 25.30(i), that this action ''is of a type that does not individually or cumulatively have a significant effect on the human environment because the amendments are administrative in nature'' such that neither an environmental assessment nor an environmental impact statement is required. Upon further consideration, we determined that FAP 7A4818 is not solely administrative in nature as this revision has the potential to lead to manufacturing changes. Consequently, the action being requested is neither a correction nor technical change and the original categorical exclusion (21 CFR 25.30(i)) is not appropriate. Therefore, we have determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment because the added vitamin D_3 and calcium will remain in the fruit juice and fruit juice drinks through ingestion by consumers and neither food additive is intended to replace macronutrients. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

IX. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Amend § 172.380 by revising paragraphs (b) and (c)(1) through (2) to read as follows:

§ 172.380 Vitamin D_3.

* * * * *

(b) Vitamin D_3 meets the specifications of ''Vitamin D_3,'', Food Chemicals Codex, 11th ed., copyright 2018, pp. 1243–1244, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or 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.*

(c) * * *

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 330 milligrams (mg) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under § 170.3(n)(35) of this chapter) that

are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

* * * * *

Dated: September 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20375 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0273]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Palm Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the operation of the Flagler Memorial (SR A1A) Bridge, mile 1021.8, the Royal Park (SR 704) Bridge, mile 1022.6, and the Southern Boulevard (SR 700/80) Bridge, mile 1024.7, across the Atlantic Intracoastal Waterway, at West Palm Beach, Florida. This modification allows the Flagler Memorial, Royal Park and Southern Boulevard Bridges to operate on alternative schedules when the President of the United States, members of the First Family, or other persons under the protection of the Secret Service visit Mar-a-Lago. The modifications are necessary to accommodate the increase in vehicular traffic when the presidential motorcade is in transit.

DATES: This rule is effective on September 20, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Type USCG–2017–0273 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email CWO4 Robert Wooten, Coast Guard Sector Miami, FL, Waterways Management Division, telephone 305–535–4311, email *robert.a.wooten@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
FL Florida
FDOT Florida Department of Transportation
AICW Atlantic Intracoastal Waterway

II. Background Information and Regulatory History

On August 17, 2017, the Coast Guard published a notice of deviation from drawbridge regulation with request for comments in the **Federal Register** (82 FR 39019) to test proposed changes. Three comments were received. Due to delays in processing this proposed regulatory change, on March 6, 2018, the Coast Guard published a notice of deviation from regulations with request for comments extension in the **Federal Register** (82 FR 9431) to allow for additional time for the public to comment. One comment was received. On May 21, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Palm Beach, FL in the **Federal Register** (83 FR 23398). No comments were received. Due to delays in processing this regulatory change, on June 25, 2018, the Coast Guard published a notice of deviation from regulations with request for comments extension in the **Federal Register** (83 FR 29438) to allow additional time for public comment and to evaluate the changes to the operating schedules with the establishment of the Presidential Security Zone (82 FR 17295). No comments were received.

We are issuing rule under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The notice of deviation published in the **Federal Register** (83 FR 29438) expires on August 29, 2018 and this rule must be in effect immediately thereafter.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The Flagler Memorial (SR A1A) Bridge, mile 1021.8, across the AICW (Lake Worth Lagoon) at West Palm Beach, Florida is a double-leaf bascule bridge that has a vertical clearance of 22 feet at mean high water in the closed position. The Royal Park (SR 704) Bridge, mile 1022.6, across the AICW (Lake Worth Lagoon) at West Palm Beach, Florida is a double-leaf bascule bridge that has a vertical clearance of 21 feet at mean high water in the closed position. The Southern Boulevard (SR 700/80) Bridge, mile 1024.7, across the AICW (Lake Worth Lagoon) at West Palm Beach, Florida is under construction, a temporary lift bridge is in place that has a vertical clearance of 14 feet at mean high water in the closed position and a 65 foot vertical clearance in the open position. The existing regulations are published in 33 CFR 117.261(u), Flagler Memorial Bridge, § 117.261(v) Royal Park Bridge, and § 117.261(w) Southern Boulevard Bridge.

The bridge owner, Florida Department of Transportation, requested changes to the drawbridge operating schedules to better facilitate orderly vehicle traffic flow across the Flagler Memorial, Royal Park and Southern Boulevard bridges when the President of the United States, members of the First Family, or other persons under the protection of the Secret Service visit Mar-a-Lago. The increase in traffic congestion occurs when the Presidential Security Zone (82 FR 17295) is enforced which closes the Southern Boulevard Bridge when the presidential motorcade is in transit. This action requires through traffic to use the Flagler Memorial and Royal Park Bridges.

IV. Discussion of Comments, Changes and the Final Rule

As noted above, we received four comments total on the two notices of deviation published on August 17, 2017 and March 6, 2018, respectively. Of the four comments received, one was a political statement with no relevance on the proposed regulation. Three of the four comments received were in favor of the regulation. Two of the comments in favor of the regulation suggested the changes be made permanent regardless of presidential visits. The Coast Guard has considered this recommendation, however, making the modified operating schedule permanent would place an unreasonable burden on navigation and potentially have a negative impact on safe navigation. The modified schedule is only in effect when uninterrupted transit of dignitaries are crossing the Southern Boulevard Bridge. While vessels may have to wait up to an hour, it is only during the weekdays and for a short period.

V. Regulatory Analyses

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

Executive Orders, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

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

This regulatory action determination is based on the ability that vessels able to pass through the Flagler Memorial and Royal Park Bridges in the closed position may do so at any time. The bridges will be able to open for emergencies. The Southern Boulevard Bridge will be under the control of the on-scene designated representative when the Presidential Security Zone is enforced.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

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

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

G. Protest Activities

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

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

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

■ 2. Amend § 117.261 by revising paragraphs (u), (v), and (w) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway From St. Marys River to Key Largo.

* * * * *

(u) *Flagler Memorial (SR A1A) Bridge, mile 1021.8, at West Palm Beach.* (1) The draw shall open on the quarter and three-quarter hour.

(2) When the security zone is enforced, the draw is allowed to remain closed to navigation from 2:15 p.m. to 5:30 p.m. with the exception of a once an hour opening at 2:15 p.m., 3:15 p.m., 4:15 p.m. and 5:15 p.m., weekdays only, if vessels are requesting an opening. At all other times the draw shall open on the quarter and three-quarter hour.

(v) *Royal Park (SR 704) Bridge, mile 1022.6, at West Palm Beach.* (1) The draw shall open on the hour and half-hour.

(2) When the security zone is enforced, the draw is allowed to remain closed to navigation from 2:15 p.m. to 5:30 p.m. with the exception of a once an hour opening at 2:30 p.m., 3:30 p.m., 4:30 p.m. and 5:30 p.m., weekdays only, if vessels are requesting an opening. At all other times the draw shall open on the hour and half-hour.

(w) *Southern Boulevard (SR 700/80) Bridge, mile 1024.7, at West Palm Beach.* (1) The draw shall open on the quarter and three-quarter hour.

(2) When the security zone is enforced, the draw may be closed without advance notice to permit uninterrupted transit of dignitaries across the bridge. At all other times the bridge shall open on the quarter and three-quarter hour, or as directed by the on-scene designated representative.

* * * * *

Dated: August 31, 2018.

James A. Passarelli,

Captain, U.S. Coast Guard Commander, Seventh Coast Guard District, Acting.

[FR Doc. 2018–20500 Filed 9–19–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0860]

RIN 1625–AA00

Safety Zone; C&S Worldwide Holdings Inc. Fireworks, Lake Ontario, Oswego, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 280-foot radius of the launch site located at 104 Bayshore Rd., Oswego, NY. This safety zone is intended to restrict vessels form portions of Lake Ontario during the C&S Worldwide Holdings Inc. fireworks display. This temporary safety zone is necessary to protect mariners and vessels from the navigational hazards associated with a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Buffalo.

DATES: This rule is effective from 7:30 p.m. until 8:30 p.m. on September 21, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0860 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 LTJG Sean Dolan, Chief Waterways Management Division, U.S. Coast Guard; telephone 716–843–9322, email *D09-SMB-SECBuffalo-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event sponsor did not submit notice to the Coast Guard with sufficient time remaining before the event to publish an NPRM. Delaying the effective date would be contrary to the rule's objectives of enhancing safety of life on the navigable water and protection of persons and vessels in vicinity of the fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the rule's objectives of enhancing safety of life on the navigable waters and protection of persons and vessels in vicinity of the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C 1231. The Captain of the Port Buffalo (COTP) has determined that a fireworks display presents significant risks to the public safety and property. Such hazards include premature and accidental detonations, dangerous projectiles, and falling or burning debris. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display takes place.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on September 21, 2018, from 7:30 p.m. until 8:30 p.m. The safety zone will encompass all waters of Lake Ontario, Oswego, NY contained within a 280-foot radius of: 43°30′43.30″ N, 76°26′2.70″ W.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

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 conclusion that this rule is not a significant regulatory action. We anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a relatively short time. Also, the safety zone has been designed to allow vessels

to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

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 establishes a temporary safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration 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: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0860 to read as follows:

§ 165.T09–0860 Safety Zone; C&S Worldwide Holdings Inc. fireworks, Lake Ontario, Oswego, NY.

(a) *Location.* The safety zone will encompass all waters of Lake Ontario; Oswego, NY contained within a 280-foot radius of: 43°30′43.30″ N, 76°26′2.70″ W.

(b) *Enforcement period.* This regulation will be enforced from 7:30 p.m. until 8:30 p.m. on September 21, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain

permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: September 14, 2018.

Joseph S. Dufresne,

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

[FR Doc. 2018–20455 Filed 9–19–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2018–0389; FRL–9983–50—Region 8]

Approval and Promulgation of Air Quality Implementation Plans; Wyoming; Incorporation by Reference Updates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving eight State Implementation Plan (SIP) revisions submitted by the State of Wyoming; four submitted on March 27, 2017, and four submitted on March 28, 2018. The revisions include updates to incorporation by reference within several parts of the Wyoming Air Quality Standards and Regulations that are part of the SIP. Additional revisions are being approved that: Correct an inconsistency regarding internal combustion engine nitrogen oxide requirements; amend three state regulations to maintain consistency with federal regulations; and update a state internet address.

DATES: This final rule is effective on October 22, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2018–0389. 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.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *www.regulations.gov*, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Chris Dresser, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6385, *dresser.chris@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

In a rulemaking published on July 23, 2018 (83 FR 34811), the EPA proposed approval of eight revisions to the Wyoming Air Quality Standards and Regulations submitted by the State of Wyoming; four submitted on March 27, 2017, and four submitted on March 28, 2018. The revisions include updates to incorporation by reference within several parts of the Wyoming Air Quality Standards and Regulations that are part of the SIP. Additional revisions were proposed that: (1) Correct an inconsistency regarding internal combustion engine nitrogen oxide requirements; (2) amend three state regulations to maintain consistency with federal regulations; and (3) update a state internet address. In this rulemaking the EPA is taking final action to approve the proposed revisions. The reasons for our approval are provided in the proposed rule.

II. Response to Public Comments

The EPA received three anonymous comments on the proposed SIP amendments to the Wyoming Air Quality Standards and Regulations. After reviewing the comments, the EPA has determined that the comments are outside the scope of our proposed action or fail to identify any material issue necessitating a response. All comments received on this action are available for review in the docket for this rulemaking. This rule will be finalized as proposed without revisions.

III. Final Action

For the reasons expressed in the proposed rule, the EPA is approving the eight SIP submittals to the Wyoming Air Quality Standards and Regulations submitted by the State of Wyoming on March 27, 2017, and March 28, 2018. This action updates: (1) Chapter 8 Non-attainment Area Regulations, Section 10, Incorporation by reference (2017 Submittal); (2) Chapter 8, Non-attainment Area Regulations, Section 3, Conformity of general federal actions to state implementation plans (2018 Submittal), and Section 10, Incorporation by reference (2018 Submittal); (3) Chapter 6, Permitting Requirements, Section 4, Prevention of significant deterioration, to remove an outdated **Federal Register** citation under the definition of 'tpy CO_2 equivalent emission (CO_2e),' portions of which had been approved in a previous October 12, 2016 EPA action (2017 Submittal); (4) Chapter 6, Permitting Requirements, Section 14, Incorporation by reference (2018 Submittal); (5) Chapter 3, General Emission Standards, Section 3, Emission standards for nitrogen oxides, which corrects an inconsistency regarding internal combustion engines (2017 Submittal); (6) Chapter 3, General Emission Standards, Section 9, Incorporation by reference (2018 Submittal); (7) Chapter 2, Ambient Standards, Section 6, Ambient Standards for ozone, to include the latest ozone NAAQS (2017 Submittal); and (8) Chapter 2, Ambient Standards, Section 12, Incorporation by reference (2018 Submittal).

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of Wyoming Air Quality Standards and Regulations described in the amendments set forth to 40 CFR part 52, below. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

V. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations (42 U.S.C. 7410(k), 40 CFR 52.02(a)). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this final action merely approves some state law as meeting federal requirements; this final

[1] 62 FR 27968 (May 22, 1997).

action does not impose additional requirements beyond those imposed by state law. For that reason, this final action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, Oct. 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- This action is not an Executive Order 13771 (82 FR 9339, Feb. 2, 2017) regulatory action because actions such as approving SIPs are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, Aug. 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, Feb. 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 19, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: September 14, 2018.

Douglas Benevento,

Regional Administrator, Region 8.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart ZZ—Wyoming

■ 2. In § 52.2620, the table in paragraph (c) is amended by revising:

■ a. Under the center heading ''Chapter 02, Ambient Standards,'' the table entries for *Section 06* and *Section 12;*

■ b. Under the center heading ''Chapter 03, General Emission Standards,'' the table entries for *Section 03* and *Section 09;*

■ c. Under the center heading ''Chapter 06, Permitting Requirements,'' *Section 04* and *Section 14;* and

■ d. Under the center heading ''Chapter 08, Non-attainment Area Regulations,'' *Section 03* and *Section 10.*

The revisions read as follows:

§ 52.2620 Identification of plan.

* * * * *

(c) * * *

Rule No.	Rule title	State effective date	EPA effective date	Final rule citation/date	Comments
*	*	*	*	*	*
Chapter 02. Ambient Standards					
*	*	*	*	*	*
Section 06	Ambient Standards for ozone	12/20/2016	10/22/2018	[Insert **Federal Register** citation]. 9/20/2018.	
*	*	*	*	*	*
Section 12	Incorporation by reference	2/5/2018	10/22/2018	[Insert **Federal Register** citation]. 9/20/2018.	
Chapter 03. General Emission Standards					

Rule No.	Rule title	State effective date	EPA effective date	Final rule citation/date	Comments
*	* * *	*	*	* *	*
Section 03	Emission standards for nitrogen oxides.	12/20/2016	10/22/2018	[Insert **Federal Register** citation]. 9/20/2018.	
*	* * *	*	*	* *	*
Section 09	Incorporation by reference	2/5/2018	10/22/2018	[Insert **Federal Register** citation]. 9/20/2018.	
*	* * *	*	*	* *	*
Chapter 06. Permitting Requirements					
*	* * *	*	*	* *	*
Section 04	Prevention of significant deterioration	12/20/2016	10/22/2018	[Insert **Federal Register** citation]. September 20, 2018.	
*	* * *	*	*	* *	*
Section 14	Incorporation by reference	2/5/2018	10/22/2018	[Insert **Federal Register** citation]. September 20, 2018.	
*	* * *	*	*	* *	*
Chapter 08. Non-attainment Area Regulations					
*	* * *	*	*	* *	*
Section 03	Conformity of general federal actions to state implementation plans.	2/5/2018	10/22/2018	[Insert **Federal Register** citation]. September 20, 2018.	
*	* * *	*	*	* *	*
Section 10	Incorporation by reference	2/5/2018	10/22/2018	[Insert **Federal Register** citation]. September 20, 2018.	
*	* * *	*	*	* *	*

* * * * *

[FR Doc. 2018–20447 Filed 9–19–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2018–0388–0001; FRL–9983–73—Region 8]

Air Quality State Implementation Plans; Approvals and Promulgations: Infrastructure Monitoring Requirements for the 2008 Pb, 2010 SO_2, 2010 NO_2 and 2012 $PM_{2.5}$ National Ambient Air Quality Standards; Utah

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of State Implementation Plan (SIP) revisions from the State of Utah to demonstrate the State meets infrastructure monitoring requirements of the Clean Air Act (Act or CAA) for the National Ambient Air Quality Standards (NAAQS) promulgated for lead (Pb) on October 15, 2008, nitrogen dioxide (NO_2) on January 22, 2010, sulfur dioxide (SO_2) on June 2, 2010, and fine particulate matter ($PM_{2.5}$) on December 14, 2012. The EPA is taking this action pursuant to section 110 of the Clean Air Act (CAA).

DATES: This rule is effective on October 22, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2018–0388–0001. 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.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Kate Gregory, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6175, *gregory.kate@epa.gov.*

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

I. Background

The background for this action is discussed in detail in our July 23, 2018 proposal (83 FR 34816). In that document we proposed to approve the State's submittal in reference to infrastructure requirements for CAA section 110(a)(2)(B), element B: Ambient air quality monitoring/data system. In the proposal, we find that Utah's SIP and practices are adequate for the

ambient air quality monitoring and data system requirements and therefore propose to approve the infrastructure SIP for the 2008 Pb, 2010 SO_2, 2010 NO_2 and 2012 $PM_{2.5}$ NAAQS for this element.

II. Response to Comments

The EPA received six anonymous comments on the proposal. After reviewing the comments, the EPA has determined that the comments are outside the scope of our proposed action or fail to identify any material issue necessitating a response. All comments received on this action are available for review in the docket for this rulemaking. This rule will be finalized as proposed without revisions.

III. Final Action

We are approving infrastructure element B for the 2008 Pb, 2010 SO_2, 2010 NO_2 and 2012 $PM_{2.5}$ NAAQS from the State's certifications as shown in Table 1.

TABLE 1—LIST OF UTAH INFRASTRUCTURE ELEMENTS THAT THE EPA IS APPROVING

Approval	Element
January 19, 2012 submittal—2008 Pb NAAQS	(B)
January 31, 2013 submittal—2010 NO_2 NAAQS	(B)
June 2, 2013 submittal—2010 SO_2 NAAQS	(B)
December 4, 2015 submittal—2012 $PM_{2.5}$ NAAQS	(B)

For the basis of our approval, please refer to the July 23, 2018 proposal (83 FR 34816).

IV. 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 19, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Greenhouse gases, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 14, 2018.

Douglas Benevento,

Regional Administrator, Region 8.

40 CFR part 52 is amended to follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart TT—Utah

■ 2. Section 52.2355 is amended by adding paragraph (d) to read as follows:

§ 52.2355 Section 110(a)(2) infrastructure requirements.

* * * * *

(d) The Utah Department of Environmental Quality submitted certification of Utah's infrastructure SIP for the 2008 Pb NAAQS on January 19, 2012; 2010 NO_2 NAAQS on January 31, 2013; 2010 SO_2 NAAQS on June 2, 2013; and 2012 $PM_{2.5}$ on December 4, 2015. Utah's infrastructure certifications demonstrate how the State, where applicable, has plans in place that meet the requirements of section 110 for the 2008 Pb, 2010 NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS. The State's Infrastructure SIP for 2008 Pb, 2010

NO_2, 2010 SO_2 and 2012 $PM_{2.5}$ NAAQS is approved with respect to 110(a)(2)(B).

[FR Doc. 2018–20448 Filed 9–19–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0061; FRL–9983–83—Region 10]

Air Plan Approval; Washington; Interstate Transport Requirements for the 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Clean Air Act (CAA) requires each State Implementation Plan (SIP) to contain adequate provisions prohibiting emissions that will have certain adverse air quality effects in other states. On February 7, 2018, the State of Washington made a submittal to the Environmental Protection Agency (EPA) to address these requirements for the 2015 ozone National Ambient Air Quality Standards (NAAQS). The EPA is approving the submittal as meeting the requirement that each SIP contain adequate provisions to prohibit emissions that will significantly contribute to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state.

DATES: This final rule is effective October 22, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2018–0061. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and is publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt at (206) 553–0256, or *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

I. Background Information

On July 23, 2018, the EPA proposed to approve Washington as meeting the requirement that each SIP contain adequate provisions to prohibit emissions that will contribute significantly to nonattainment or interfere with maintenance of the 2015 ozone NAAQS in any other state (83 FR 34813). An explanation of the Clean Air Act requirements, a detailed analysis of the submittal, and the EPA's reasons for proposing approval were provided in the notice of proposed rulemaking, and will not be restated here. The public comment period for the proposal ended August 22, 2018.

II. Response to Comments

We received several anonymous comments unrelated to Washington's submission. After reviewing the anonymous comments, we have determined that the comments are outside the scope of our proposed action and fail to identify any material issue necessitating a response. For more information, please see our memorandum included in the docket for this action.

III. Final Action

The EPA is approving Washington's February 7, 2018, submittal certifying that the SIP is sufficient to meet the interstate transport requirements of Clean Air Act section 110(a)(2)(D)(i)(I) for the 2015 ozone NAAQS.

IV. 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 Clean Air 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);
- is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because actions such as SIP approvals are exempted under Executive Order 12866;
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; 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).

The SIP is not approved to apply on any Indian reservation land and is also not approved to apply 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of

this action must be filed in the United States Court of Appeals for the appropriate circuit by November 19, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: September 5, 2018.

Chris Hladick,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart WW—Washington

■ 2. In § 52.2470, table 2 in paragraph (e) is amended by adding the entry for ''Interstate Transport for the 2015 Ozone NAAQS'' immediately below the entry for ''Interstate Transport for the 2012 $PM_{2.5}$ NAAQS'' to read as follows:

§ 52.2470 Identification of plan.

* * * * *

(e) * * *

TABLE 2—ATTAINMENT, MAINTENANCE, AND OTHER PLANS

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
* * * * * * *				
Interstate Transport for the 2015 Ozone NAAQS.	Statewide	2/7/2018	9/20/2018, [Insert **Federal Register** citation].	This action addresses CAA 110(a)(2)(D)(i)(I).
* * * * * * *				

[FR Doc. 2018–20389 Filed 9–19–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2017–0435; FRL–9983–35—Region 6]

Approval and Promulgation of Implementation Plans; Arkansas; Interstate Transport Requirements for the 2012 $PM_{2.5}$ NAAQS and Definition Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is approving portions of the Arkansas State Implementation Plan (SIP) submittal addressing the CAA requirement that SIPs address the potential for interstate transport of air pollution to significantly contribute to nonattainment or interfere with maintenance of the 2012 fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) in other states. EPA finds that emissions from Arkansas sources do not contribute significantly to nonattainment in, or interfere with maintenance by, any other state with regard to the 2012 $PM_{2.5}$ NAAQS. The EPA is also approving a revision to update incorporation by reference of NAAQS germane to the Arkansas SIP.

DATES: This final rule is effective on November 7, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No EPA–R06–OAR–2017–0435. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Sherry Fuerst, 214–665–6454, *fuerst.sherry@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' means the EPA. We selected a November 7, 2018 effective date for this final rule in order for the CFR to reflect this approval and our August 8, 2018 approval of Arkansas Regulation 19 Chapter 2 (83 FR 38964) which has an effective date of November 6, 2018.

I. Background

The background for this action is discussed in detail in our June 26, 2018 proposal (83 FR 30622). In that document we proposed to approve portions of Arkansas' State Implementation Plan (SIP) March 24, 2017 submittal, that addresses a CAA requirement that SIPs account for potential interstate transport of air pollution that significantly contributes to nonattainment or interferes with maintenance of the 2012 $PM_{2.5}$ NAAQS in other states. We proposed to determine that emissions from Arkansas sources do not contribute significantly to nonattainment in, or interfere with maintenance by, any other state with regard to the 2012 $PM_{2.5}$ NAAQS. We also proposed to approve updates to that

definition of NAAQS and the NAAQS list.[1]

We received four anonymous public comments on the proposed rulemaking action. The comments are posted to the docket (EPA–R06–OAR–2017–0435). In the first comment, received on July 31, 2018, the commenter discusses the costs of renewable energy in Europe and in the northeast United States. Such comment is irrelevant and is outside the scope of this specific rule making action. In the second comment, received July 31, 2018 the commenter discusses the use of child labor in rare earth mining, and the dangers associated with this type of mining. Such comment is irrelevant and outside the scope of this specific rule making action. In the third comment, received July 31, 2018 the commenter discusses the CO2 emissions produced by forest fires. Such comment is irrelevant and outside the scope of this specific rule making action. In the fourth comment, received on July 31, 2018, the commenter provided personal observations regarding the Administration. Such comments are irrelevant and outside the scope of this specific rule making action. Since these comments are not relevant to the specific action EPA proposed, the EPA will not be responding to these comments or making any changes to our proposed rulemaking.

II. Final Action

Pursuant to section 110 of the CAA we are approving the following revisions to the Arkansas SIP submitted on March 24, 2017:

- The portion of the Arkansas SIP submittal, pertaining to interstate transport of air pollution, that establishes emissions from Arkansas will not significantly contribute to nonattainment or interfere with maintenance of the 2012 $PM_{2.5}$ NAAQS in any other state.
- The portion of the Arkansas SIP submittal that revised the definition of NAAQS in Regulation 19, Chapter 2 and revised the entry for ''Particle Pollution, $PM_{2.5}$'' in Regulation 19, Appendix B.

We find that emissions from Arkansas sources do not contribute significantly to nonattainment in, or interfere with maintenance by, any other state with regard to the 2012 $PM_{2.5}$ NAAQS.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the revisions to the Arkansas regulations as described in the Final Action section above. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 6 Office (please contact Sherry Fuerst, 214–665–6454, *fuerst.sherry@epa.gov* for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.

V. Statutory and Executive Order Reviews

Under the 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 19, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

[1] In a separate action we approved other revisions to definitions in the Arkansas SIP (83 FR 38964, August 8, 2018).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

Dated: September 13, 2018.

Anne Idsal,

Regional Administrator, Region 6.

Therefore, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart E—Arkansas

■ 2. In § 52.170:

■ a. In paragraph (c), the table titled ''EPA-Approved Regulations in the Arkansas SIP'' is amended by revising the entries under Regulation 19 for Chapter 2 and Appendix B; and

■ b. I paragraph (e), the second table titled ''EPA-Approved Non-Regulatory Provisions and Quasi-Regulatory Measures in the Arkansas SIP'' is amended by revising the entry for ''Infrastructure for the 2012 $PM_{2.5}$ NAAQS''.

The revisions read as follows:

§ 52.170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP

State citation	Title/subject	State submittal/ effective date	EPA approval date	Explanation
Regulation No. 19: Regulations of the Arkansas Plan of Implementation for Air Pollution Control				
*	*	*	*	*
Chapter 2: Definitions				
Chapter 2	Definitions	3/24/2017	8/8/2018, 83 FR 38964	The definition of VOC was approved on 12/21/2017 (82 FR 60517). The definition of National Ambient Air Quality Standards was approved on 9/20/2018, [Insert **Federal Register** citation].
*	*	*	*	*
Appendix B: National Ambient Air Quality Standards List				
Appendix B	National Ambient Air Quality Standards List.	3/24/2017	8/8/2018, 83 FR 38964	The revision to Particle Pollution, $PM_{2.5}$ was approved on 9/20/2018, [Insert **Federal Register** citation].
*	*	*	*	*

(e) * * *

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

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Explanation
*	*	*	*	*
Infrastructure for the 2012 $PM_{2.5}$ NAAQS.	Statewide	3/24/2017	2/14/2018, 83 FR 6470	Approval for 110(a)(2)(A), (B), (C), (D)(i) (portion pertaining to PSD), (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M). Approval for 110(a)(2)(D)(i)(I) (significant contribution to nonattainment or interfere with maintenance in any other state) on 9/20/2018, [Insert **Federal Register** citation].

[FR Doc. 2018–20480 Filed 9–19–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R07–OAR–2017–0349; FRL–9983–68—Region 7]

Approval of Missouri Air Quality Implementation Plans; Redesignation of the Missouri Portion of the St. Louis-St. Charles-Farmington, MO-IL 2008 Ozone Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to redesignate the Missouri portion of the St. Louis-St. Charles-Farmington, MO-IL nonattainment area (''St. Louis area'' or ''area'') to attainment for the 2008 ozone National Ambient Air Quality Standard (NAAQS). EPA is also approving, as a revision to the Missouri State Implementation Plan (SIP), the state's plan for maintaining the 2008 8-hour ozone NAAQS through 2030. Finally, EPA finds adequate and is approving, as a SIP revision, the State's 2030 volatile organic compound (VOC) and oxides of nitrogen (NO_X) Motor Vehicle Emission Budgets (MVEBs) for the Missouri portion of the St. Louis area. The Missouri Department of Natural Resources (MDNR) submitted this request on September 12, 2016, with a supplemental submission on February 16, 2018. EPA addressed the Illinois portion of the St. Louis area in a separate rulemaking action published in the **Federal Register** on March 1, 2018.

DATES: This final rule is effective on September 20, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2017–0349. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Lachala Kemp, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7214, or by email at *kemp.lachala@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' refer to EPA. This section provides additional information by addressing the following:

Table of Contents

I. What is being addressed in this document?

This final rulemaking takes final action on submissions from MDNR dated September 12, 2016, and supplemented on February 16, 2018, requesting redesignation of the Missouri portion of the St. Louis area attainment for the 2008 ozone NAAQS. The background for this action is discussed in detail in EPA's proposed rulemaking published in the **Federal Register** on June 25, 2018 (83 FR 29486). In that proposed rulemaking we noted, under EPA's regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the three-year average of the annual fourth highest daily maximum 8-hour average concentration is equal to or less than 0.075 ppm at all of the ozone monitoring sites in the area. *See* 40 CFR 50.15 and appendix P to 40 CFR part 50. Under the CAA, EPA may redesignate nonattainment areas to attainment if sufficient complete, quality-assured data are available to determine that the area has attained the standard and if it meets the other CAA redesignation requirements in section 107(d)(3)(E). The proposed rule provides a detailed discussion of how Missouri has met these CAA requirements.

As discussed in the June 25, 2018, proposal, quality-assured and certified monitoring data for 2013–2015 show that the St. Louis area has attained the 2008 ozone standard. In the maintenance plan submitted for the area, Missouri has demonstrated that the ozone standard will be maintained in the area through 2030. Finally, Missouri adopted 2030 MVEBs for its portion of the St. Louis area that are adequate and supported by MDNR's maintenance demonstration.

II. Have the requirements for approval of a SIP revision been met?

The state's submission has met the public notice requirements for the redesignation request and maintenance plan submission in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The state held a public comment period from June 27, 2016, to August 4, 2016, and received six comments from three commenters. A public hearing was held on July 28, 2016.

III. EPA's Response to Comments

EPA provided a thirty-day review and comment period for the June 25, 2018 proposed rule. The comment period ended on July 25, 2018. EPA received three sets of comments, specifically adverse comments from the Missouri Department of Natural Resources (MDNR) and the Sierra Club. Full sets of these comments are provided in the docket for this final action. A summary of the adverse comments and EPA's responses are provided below.

Comment: The commenter stated that Missouri's most recent monitoring network plan was approved in 2017, as also stated in the proposal. However, a footnote in the proposal references the 2016 monitoring network plan and the state's commitment to verified attainment. The commenter is requesting the footnote reference be changed to reflect the most recent approved plan.

EPA's Response: EPA agrees with the commenter that the most recent monitoring network plan was approved on December 19, 2017, and Missouri has committed to monitoring air quality for verification of continued attainment. In this final rulemaking notice, we clarify that the monitoring network plan used for verification of continued attainment is the plan approved by EPA on December 19, 2017.

Comment: The commenter requested clarification on the source of the 2014 attainment inventory data, since the proposal states that data for the 2014 attainment inventory was not interpolated between the 2011 and 2018 Ozone NAAQS Emissions Modeling platform inventories, because EPA's National Emissions Inventory (NEI) was unavailable at the time of the redesignation request.

EPA's Response: EPA agrees with the commenter that the Agency's 2014 NEI was not available at the time Missouri submitted its request for redesignation. EPA also agrees that Missouri did not interpolate data between 2011 and 2018 to create inventories for 2014. The state used Missouri-specific 2014 emissions data for the 2014 attainment year. As indicated in the proposal both NO_X and VOC emissions decreased from the base year to the attainment year and helps adequately demonstrate that

improvement in air quality is due to permanent and enforceable emission reductions.

Comment: The commenter stated that EPA should not take final action to approve the redesignation of the St. Louis area to attainment because the state's data indicate most monitoring sites in the nonattainment area have exceeded the 2008 ozone NAAQS in just the first half of the 2018 ozone season, and that past improvements cannot be reasonably attributed to permanent and enforceable reductions in emissions because of regular exceedances of the 2008 NAAQS at monitoring sites.

EPA's Response: Section 107(d)(3)(E) of the CAA allows redesignation of a nonattainment area to attainment of the NAAQS provided that: (1) The Administrator determines that the area has attained the NAAQS; (2) the Administrator has fully approved the applicable implementation plan for the area under section 110(k) of the CAA; (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP, applicable Federal air pollutant control regulations, and other permanent and enforceable emission reductions; (4) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA; and (5) the state containing the area has met all requirements applicable to the area for the purposes of redesignation under section 110 and part D of the CAA. Specifically, the CAA section 107(d)(3)(E)(i) requires EPA to determine that the area has attained the applicable NAAQS. An area is attaining the 2008 ozone NAAQS if it meets the 2008 ozone NAAQS, as determined in accordance with 40 CFR 50.15 and appendix P of part 50, based on three complete, consecutive calendar years of quality assured air quality data for all monitoring sites in the area. To attain the NAAQS, the three-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations (ozone design values) at each monitor must not exceed 0.075 ppm. EPA disagrees with the commenter that final action should not be taken to redesignate the St. Louis area due to data indicating exceedances at monitoring sites in the area.

EPA's proposed rulemaking was based on quality assured data from 2013–2015 which demonstrated that the St. Louis area is attaining the 2008 ozone NAAQS. In addition, 2014–2016 and 2015–2017 data confirm that the area continues to attain that NAAQS. EPA's ozone season runs from March–October and data collected thus far in 2018 has yet to be quality assured or certified by the state. Individual readings at air quality monitors that exceed the level of the NAAQS do not mean that an area is no longer attaining the NAAQS. In part because ozone concentrations are influenced by meteorology and subject to variable conditions, attainment of the 2008 ozone NAAQS is measured using the three-year average design value at all monitoring sites in the area. Moreover, as stated in the proposal, the St. Louis area has also shown a decrease in both NO_X and VOC emissions which indicates that improvement in air quality is due to permanent and enforceable emission reductions, rather than temporary conditions.

IV. What action is EPA taking?

EPA has determined that the Missouri portion of the St. Louis nonattainment area is attaining the 2008 ozone standard based on quality-assured and certified monitoring data for 2013–2015 and that the Missouri portion of the St. Louis area has met the requirements for redesignation under section 107(d)(3)(E) of the CAA.

EPA is thus approving the state's request to change the designation of the Missouri portion of the St. Louis area for the 2008 ozone standard from nonattainment to attainment. EPA is also approving, as a revision to the Missouri SIP, the state's maintenance plan for the area. The maintenance plan is designed to keep the Missouri portion of the St. Louis area in attainment of the 2008 ozone NAAQS through 2030. Finally, EPA finds adequate and is approving the newly-established 2030 MVEBs for the Missouri portion of the St. Louis area.

EPA has determined that these actions are effective immediately upon publication under the authority of 5 U.S.C. 553(d). The purpose of the thirty-day waiting period prescribed in section 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Section 553(d)(1) allows an effective date less than thirty days after publication if a substantive rule ''relieves a restriction.'' These actions qualify for the exception under section 553(d)(1) because they relieve the State of various requirements for the Area. Furthermore, section 553(d)(3) allows an effective date less than thirty days after publication ''as otherwise provided by the agency for good cause found and published with the rule.'' EPA finds good cause to make these actions effective immediately pursuant to section 553(d)(3) because they do not create any new regulatory requirements such that affected parties would need time to prepare before the actions take effect.

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 13, 2018.

James B. Gulliford,

Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 40 CFR parts 52 and 81 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart—AA Missouri

■ 2. Amend § 52.1342 by adding paragraph (e) to read as follows:

§ 52.1342 Control strategy: Ozone.

* * * * *

(e) *Redesignation to attainment.* On September 12, 2016, and February 16, 2018, Missouri submitted requests to redesignate its portion of the St. Louis MO-IL area to attainment of the 2008 ozone standard. The Missouri portion of the St. Louis MO-IL area includes Jefferson, Franklin, St. Charles, and St. Louis Counties along with the City of St. Louis. As part of the redesignation request, the State submitted a plan for maintaining the 2008 ozone standard through 2030 in the area as required by section 175A of the Clean Air Act.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

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

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

Subpart C—Section 107 Attainment Status Designations

■ 4. Section 81.326 is amended by revising the entry for ''St. Louis-St. Charles-Farmington, MO-IL'' in the table entitled ''Missouri—2008 8-Hour Ozone NAAQS (Primary and Secondary)'' to read as follows:

§ 81.326 Missouri.

* * * * *

MISSOURI—2008 8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
St. Louis-St. Charles-Farmington, MO-IL [2]:				
Franklin County	9/20/2018	Attainment.		
Jefferson County	9/20/2018	Attainment.		
St. Charles County	9/20/2018	Attainment.		
St. Louis County	9/20/2018	Attainment.		
St. Louis City	9/20/2018	Attainment.		
* * * * *				

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2018–20326 Filed 9–19–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 639

[Docket No. FTA–2018–0006]

RIN 2132–AB34

Capital Leases

AGENCY: Federal Transit Administration (FTA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This rulemaking rescinds the regulation implementing the requirement for recipients to conduct a cost-effectiveness analysis before leasing public transportation equipment or facilities with Federal transit funds. The requirement to conduct a cost-effectiveness analysis was rescinded by statute in 2015.

DATES: This final rule is effective on September 20, 2018.

FOR FURTHER INFORMATION CONTACT: Mark Montgomery, Office of Chief

Counsel, (202) 366–1017 or *mark.montgomery@dot.gov.* Office hours are from 9 a.m. to 5:30 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document is viewable online through the Federal eRulemaking portal at *http://www.regulations.gov.* Retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days a year. An electronic copy of this document is available for download from the Office of the Federal Register home page at: *http://www.ofr.gov* and the Government Publishing Office web page at: *http://www.gpo.gov.*

Background

49 CFR part 639 limits capital leasing arrangements for use in public transportation to those that are more cost-effective than purchase or construction. This part implements section 3003 of the Transportation Equity Act for the 21st Century (Pub. L. 105–178) (TEA–21), which amended section 5302 of title 49, United States Code (Section 5302), to allow a recipient to use capital funds to finance the leasing of facilities and equipment on the condition that the leasing arrangements are more cost-effective than purchase or construction. This section also required the Secretary to promulgate regulations to implement the cost-effectiveness limitation. Recently, section 3002 of the Fixing America's Surface Transportation Act (Pub. L. 114–357) (FAST Act) amended the definition of ''capital project'' under section 5302 to remove this requirement and the mandate to promulgate regulations to carry out this requirement. For this reason, FTA is issuing this final rule to rescind 49 CFR part 639.

FTA will continue to evaluate its regulations and guidance to promote improvements to the capital leasing process in the least burdensome manner.

Discussion of the Changes

Under the amended statutory definition of ''capital project,'' capital leases are no longer subject to the requirement or regulation limiting leasing arrangements to those that are more cost-effective than purchase or construction. Accordingly, this rulemaking rescinds 49 CFR part 639, which outlines the procedures for conducting the cost-effectiveness analysis. This rule does not affect the general procurement standards in 2 CFR part 200, nor does it alter the award management requirements in FTA's Circular 5010.1E.

Under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), an agency may waive the normal notice and comment procedure if it finds, for good cause, that it is impracticable, unnecessary, or contrary to the public interest. Additionally, 5 U.S.C. 553(d) provides that an agency may waive the 30-day delayed effective date upon finding of good cause.

Section 3003 of TEA–21 amended section 5302 to allow a recipient to use capital funds to finance the leasing of facilities and equipment, ''subject to regulations that the Secretary prescribes limiting the leasing arrangements to those that are more cost-effective than purchase or construction.'' By removing this language, section 3002 of the FAST Act eliminated the requirement limiting capital leases to those that are more cost-effective than purchase or construction. FTA finds good cause that notice and comment for this rule is unnecessary due to the nature of the revisions (*i.e.,* the rule simply carries out the statutory language found in the FAST Act). The statutory language does not require regulatory interpretation to carry out its intent, and comments cannot alter the regulation given that the statute abrogated its purpose. Further, the delayed effective date is unnecessary because the removal of the cost-effectiveness analysis requirement was already made effective by the FAST Act. Accordingly, FTA finds good cause under 5 U.S.C. 553(b)(3)(B) and (d)(3) to waive notice and opportunity for comment and the delayed effective date.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), and Department of Transportation (DOT) Regulatory Policies and Procedures

FTA has determined that this rulemaking is not a significant regulatory action within the meaning of Executive Order 12866, and within the meaning of DOT regulatory policies and procedures. This action complies with Executive Orders 12866, 13563 and 13771 to improve regulation.

FTA classifies this rule as a deregulatory action under Executive Order 13771, because it removes the mandatory cost-effectiveness analysis. FTA finds that the cost savings are minor. On average, there are twelve leases per year subject to the requirement, and the analysis takes approximately a week for transit agencies to compile and prepare and approximately eight hours for FTA to review and approve the certification. Thus, removing these requirements would provide a maximum average annual cost savings of $32,373 and impose no additional costs on recipients.

Regulatory Flexibility Act

Because FTA finds good cause under 5 U.S.C. 553(b)(3)(B) to waive notice and opportunity for comment for this rule, the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) do not apply. FTA evaluated the effects of this action on small entities and determined the action would not have a significant economic impact on a substantial number of small entities. FTA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

FTA has determined that this rule does not impose unfunded mandates, as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). This rule does not include a Federal mandate that may result in expenditures of $155.1 million or more in any 1 year (when adjusted for inflation) in 2012 dollars for either State, local, and tribal governments in the aggregate, or by the private sector. Additionally, the definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal Transit Act permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may 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. This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 dated August 4, 1999, and FTA determined this action will not have a substantial direct effect

or sufficient federalism implications on the States. FTA also determined this action will not preempt any State law or regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. FTA has analyzed this rule under the Paperwork Reduction Act and believes that it does not impose additional information collection requirements for the purposes of the Act above and beyond existing information collection clearances from OMB.

National Environmental Policy Act

Federal agencies are required to adopt implementing procedures for the National Environmental Policy Act (NEPA) that establish specific criteria for, and identification of, three classes of actions: (1) Those that normally require preparation of an Environmental Impact Statement, (2) those that normally require preparation of an Environmental Assessment, and (3) those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). This rule qualifies for categorical exclusions under 23 CFR 771.118(c)(4) (planning and administrative activities that do not involve or lead directly to construction). FTA has evaluated whether the rule will involve unusual or extraordinary circumstances and has determined that it will not.

Executive Order 12630 (Taking of Private Property)

FTA has analyzed this rule under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. FTA does not believe this rule effects a taking of private property or otherwise has taking implications under Executive Order 12630.

Executive Order 12988 (Civil Justice Reform)

This 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.

Executive Order 13045 (Protection of Children)

FTA has analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. FTA certifies that this action will not cause an environmental risk to health or safety that might disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

FTA has analyzed this rule under Executive Order 13175, dated November 6, 2000, and believes that it will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal laws. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

FTA has analyzed this action under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. FTA has determined that this action is not a significant energy action under that order and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Executive Order 12898 (Environmental Justice)

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations) and DOT Order 5610.2(a) (77 FR 27534, May 10, 2012) (available online at *http://www.fhwa.dot.gov/environment/environmental_justice/ej_at_dot/order_56102a/index.cf*) require DOT agencies to achieve Environmental Justice (EJ) as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority and low-income populations. All DOT agencies must address compliance with Executive Order 12898 and the DOT Order in all rulemaking activities. On August 15, 2012, FTA's Circular 4703.1 became effective, which contains guidance for recipients of FTA financial assistance to incorporate EJ principles into plans, projects, and activities (available online at *http://www.fta.dot.gov/documents/FTA_EJ_Circular_7.14-12_FINAL.pdf*).

FTA has evaluated this action under the Executive Order, the DOT Order, and the FTA Circular. The rule rescinds the requirement of conducting cost-effectiveness analysis for capital leases, and FTA has determined that this action will not cause disproportionately high and adverse human health and environmental effects on minority or low-income populations.

Regulation Identifier Number

A Regulation Identifier Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this rule with the Unified Agenda.

List of Subjects in 49 CFR Part 639

Grant programs—transportation, Mass transportation.

Issued in Washington, DC, under authority delegated in 49 CFR 1.90:

K. Jane Williams,

Acting Administrator.

Title 49—Transportation

PART 639—[REMOVED AND RESERVED]

■ In consideration of the foregoing, and under the authority of 49 U.S.C. 5302 and Public Law 114–357, amend 49 CFR chapter VI by removing and reserving part 639, consisting of §§ 639.1 through 639.33.

[FR Doc. 2018–20474 Filed 9–19–18; 8:45 am]

BILLING CODE P

Proposed Rules

Federal Register
Vol. 83, No. 183
Thursday, September 20, 2018

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0745; Airspace Docket No. 18–ASO–15]

RIN 2120–AA66

Proposed Amendment of Class E Airspace, Mountain City, TN; and Proposed Establishment of Class E Airspace; Elizabethton, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface in Mountain City, TN, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures serving Johnson County Airport. In addition, Class E airspace extending upward from 700 feet above the surface would be established in Elizabethton, TN to accommodate area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures at Elizabethton Municipal Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at these airports.

DATES: Comments must be received on or before November 5, 2018.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2018–0745; Airspace Docket No. 18–ASO–15, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Johnson County Airport, Mountain City, TN, and establish Class E airspace at Elizabethton Municipal, Elizabethton, TN, to support IFR operations at these airports.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2018–0745 and Airspace Docket No. 18–ASO–15) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number.) You may also submit comments through the internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2018–0745; Airspace Docket No. 18–ASO–15.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation

Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet or more above the surface at Johnson County Airport, Mountain City, TN, by increasing the northeast extension to 14.4 miles (from 10.9 miles), and creating a 14-mile extension southwest of the airport, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures at the airport.

Additionally, Class E airspace extending upward from 700 feet above the surface would be established at Elizabethton Municipal Airport, Elizabethton, TN, within a 9.5-mile radius of the airport, and within 4-miles each side of the 243° bearing from the airport, extending from the 9.5-mile radius to 15-miles southwest of the airport to accommodate RNAV (GPS) standard instrument approach procedures for IFR operations at these airports.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

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

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

* * * * *

ASO TN E5 Mountain City, TN [Amended]

Johnson County Airport, TN
(Lat. 36°25′04″ N, long. 81°49′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Johnson County Airport, and within 3.2 miles each side of the 066° bearing from the airport, extending from the 6.7-mile radius to 14.4 miles northeast of the airport, and within 3.2 miles each side of the 251° bearing from the airport, extending from the 6.7-mile radius to 14-miles southwest of the airport.

ASO TN E5 Elizabethton, TN [New]

Elizabethton Municipal Airport, TN
(Lat. 36°22′16″ N, long. 82°10′24″ W)

That airspace extending upward from 700 feet above the surface within a 9.5-mile radius of Elizabethton Municipal Airport, and within 4-miles each side of the 243° bearing from the airport, extending from the 9.5-mile radius to 15-miles southwest of the airport.

Issued in College Park, Georgia, on September 10, 2018.

Christopher Cox,

Acting Manager, Operations Support Group Eastern Service Center, Air Traffic Organization.

[FR Doc. 2018–20225 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0698; Airspace Docket No. 18–AGL–20]

RIN 2120–AA66

Proposed Amendment of Class D Airspace; Pontiac, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace at Oakland County International Airport, Pontiac, MI. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Pontiac VHF omnidirectional range (VOR) navigation aid, which provided navigation information for the instrument procedures at this airport, as part of the VOR Minimum Operational Network (MON) Program. This action would also replace the outdated term Airport/Facility Directory with Chart Supplement. Airspace redesign is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before November 5, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2018–0698; Airspace Docket No. 18–AGL–20, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between

9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D airspace at Oakland County International Airport, Pontiac, MI, to support IFR operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2018–0698; Airspace Docket No. 18–AGL–20.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Class D airspace at Oakland County International Airport, Ponitac, MI, adding an extension 1.0 mile each side of the 274° bearing from the airport extending from the 4.2-mile radius to 4.4 miles west of the airport; and adding an extension 1.0 mile each side of the 275° bearing from the Oakland County Intl: RWY 09R–LOC extending from the 4.2-mile radius to 4.4 miles west of the Oakland County Intl: RWY 09R–LOC.

This action also would make an editorial change to the airspace legal description replacing ''Airport/Facility Directory'' with ''Chart Supplement''.

This action is necessary due to an airspace review caused by the decommissioning of the Pontiac VOR, which provided navigation information to the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 5000 Class D Airspace.

* * * * *

AGL MI D Pontiac, MI [Amended]

Oakland County International Airport, MI
(Lat. 42°39′56″ N, long. 83°25′14″ W)
Oakland County Intl: RWY 09R–LOC
(Lat. 42°39′56″ N, long. 83°24′16″ W)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4.2-mile radius of Oakland County International Airport, and within 1.0 mile each side of the 274° bearing from the airport extending from the 4.2-mile radius to 4.4 miles west of the airport, and within 1.0 mile each side of the 275° bearing from the Oakland County Intl: RWY 09R–LOC extending from the 4.2-mile radius to 4.4 miles from the Oakland County Intl: RWY 09R–LOC. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in Fort Worth, Texas, on September 10, 2018.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2018–20405 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0685; Airspace Docket No. 18–AGL–19]

RIN 2120–AA66

Proposed Amendment of Class D Airspace; Detroit, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace at Coleman A. Young Municipal Airport (formerly Detroit City Airport), Detroit, MI, by changing the airspace designation to Detroit, MI, thereby removing the old airport name. The name and geographic coordinates of the airport also would be updated to coincide with the FAA's aeronautical database. This action is necessary to keep information current for the safety and management of aircraft within the national airspace system.

DATES: Comments must be received on or before November 5, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2018–0685; Airspace Docket No. 18–AGL–19, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D airspace at Coleman A. Young Memorial Airport, Detroit, MI.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2018–0685; Airspace Docket No. 18–AGL–19.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A

report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 amending the Class D airspace by updating for the location in the header of the airspace legal description to Detroit, MI (previously Detroit City Airport, MI), at Coleman A. Young Municipal Airport (formerly Detroit City Airport), Detroit, MI, to comply with FAA Order 7400.2L, Procedures for Handling Airspace Matters. The name and geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 5000 Class D Airspace.

* * * * *

AGL MI D Detroit, MI [Amended]

Coleman A. Young Municipal Airport, MI
(Lat. 42°24′34″ N, long. 83°00′36″ W)

That airspace extending upward from the surface to and including 3,100 feet MSL within a 4.1-mile radius of the Coleman A. Young Municipal Airport.

Issued in Fort Worth, Texas, on September 10, 2018.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2018–20403 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0744; Airspace Docket No. 18–ASO–14]

RIN 2120–AA66

Proposed Establishment of Class E Airspace, and Amendment of Class D Airspace and Class E Airspace; Dothan, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E surface airspace at Dothan Regional Airport, Dothan, AL. The Class E surface airspace would be established for the safety of aircraft landing and departing the airport when the air traffic control tower is closed. Also, this action proposes to amend Class D airspace by updating the airport's name and geographic coordinates, as well as replacing the outdated term 'Airport/Facility Directory' with 'Chart Supplement'. Additionally, the geographic coordinates of the airport and Wiregrass VORTAC would be adjusted in the associated Class E airspace to match the FAA's aeronautical database; as well as removing the part-time status of the airspace for Class E airspace designated as an extension to a Class D surface area. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before November 5, 2018.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Bldg. Ground Floor, Rm. W12–140, Washington, DC 20590; Telephone: 1–800–647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2018–0744; Airspace Docket No. 18–ASO–14, at the beginning of

your comments. You may also submit and review received comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish Class E surface airspace and amend Class D airspace and Class E airspace at Dothan Regional Airport, Dothan, AL, to support IFR operations at this airport.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2018–0744 and Airspace Docket No. 18–ASO–14) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number.) You may also submit comments through the internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2018–0744; Airspace Docket No. 18–ASO–14.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 by:

Amending Class D airspace at Dothan Regional Airport, Dothan, AL by recognizing the airport name change to Dothan Regional Airport (formerly Dothan Airport), and adjusting the geographic coordinates of the airport to be in concert with the FAA's aeronautical database. Also, this action would make an editorial change replacing the term ''Airport/Facility Directory'' with the term ''Chart Supplement'' in the airspace legal description;

Establishing Class E surface area airspace within a 4.7-mile radius of Dothan Regional Airport, Dothan, AL, for the safety of aircraft landing and departing the airport after the air traffic control tower closes;

Amending Class E airspace designated as an extension to a Class D surface area by adjusting the geographic coordinates of the airport and the Wiregrass VORTAC to be in concert with the FAA's aeronautical database.

In addition, the part-time status would be removed from this airspace description, as the airspace is continuously active; and

Amending Class E airspace extending upward from 700 feet above the surface at Dothan Regional Airport, Dothan, AL, by adjusting the geographic coordinates of the airport and the Wiregrass VORTAC to be in concert with the FAA's aeronautical database, and by recognizing the airport name change to Dothan Regional Airport (formerly Dothan Airport).

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 5000 Class D Airspace.

* * * * *

ASO AL D Dothan, AL [Amended]

Dothan Regional Airport, AL
(Lat. 31°19′16″ N, long. 85°26′58″ W)

That airspace extending upward from the surface to and including 2,900 feet MSL within a 4.7-mile radius of Dothan Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ASO AL E2 Dothan, AL [New]

Dothan Regional Airport, AL
(Lat. 31°19′16″ N, long. 85°26′58″ W)

That airspace extending upward from the surface within a 4.7-mile radius of Dothan Regional Airport. This Class E surface airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

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

* * * * *

ASO AL E4 Dothan, AL [Amended]

Dothan Regional Airport, AL
(Lat. 31°19′16″ N, long. 85°26′58″ W)
Wiregrass VORTAC
(Lat. 31°17′05″ N, long. 85°25′52″ W)

That airspace extending upward from the surface within 3.2 miles each side of the Wiregrass VORTAC 156° radial, extending from the 4.7-mile radius of Dothan Regional Airport to 7-miles southeast of the VORTAC.

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

* * * * *

ASO AL E5 Dothan, AL [Amended]

Dothan Regional Airport, AL
(Lat. 31°19′16″ N, long. 85°26′58″ W)
Wiregrass VORTAC
(Lat. 31°17′05″ N, long. 85°25′52″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Dothan Regional Airport within 3.2 miles each side of Wiregrass VORTAC 156° radial, extending from the 6.7-mile radius to 7 miles SE of the VORTAC excluding that airspace within the Fort Rucker, AL, Class E airspace area.

Issued in College Park, Georgia, on September 10, 2018.

Christopher Cox,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2018–20224 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0682; Airspace Docket No. 18–ACE–5]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Cabool, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface at Cabool Memorial Airport, Cabool, MO. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Maples VHF omnidirectional range (VOR) navigation aid, which provided navigation information for the instrument procedures at this airport, as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database. This action is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before November 5, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2018–0682; Airspace Docket No. 18–ACE–5 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and

subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2018–0682; Airspace Docket No. 18–ACE–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 that would amend Class E airspace extending upward from 700 feet above the surface at Cabool Memorial Airport, Cabool, MO, by removing the Maples VORTAC and associated extension northeast of the airport. This action would also update the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Maples VOR, which provided navigation information to the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

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

* * * * *

ACE MO E5 Cabool, MO [Amended]

Cabool Memorial Airport, MO
(Lat. 37°07′57″ N, long. 92°05′02″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Cabool Memorial Airport.

Issued in Fort Worth, Texas, on September 10, 2018.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2018–20398 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0699; Airspace Docket No. 18–ASW–11]

RIN 2120–AA66

Proposed Amendment of Class D and E Airspace and Revocation of Class E Airspace; Fayetteville, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace and Class E airspace designated as a surface area, and remove Class E airspace designated as an extension to a Class D and Class E airspace at Drake Field, Fayetteville, AR. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Drake VHF omnidirectional range (VOR) navigation aid, which provided navigation information for the instrument procedures at this airport, as part of the VOR Minimum Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before November 5, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2018–0699; Airspace Docket No. 18–ASW–11, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D airspace and Class E airspace designated as a surface area, and remove Class E airspace designated as an extension to a Class D and Class E airspace at Drake Field, Fayetteville, AR, to support instrument flight rule operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2018–0699/Airspace Docket No. 18–ASW–11.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal

docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by:

Amending the Class D airspace at Drake Field, Fayetteville, AR, to within a 4.0-mile radius (decreased from a 4.1-mile radius); and adding an extension 1.1 miles each side of the 181° bearing from the airport from the 4.0-mile radius to 5.9 miles north of the airport, and adding an extension 1.0 mile each side of the 172° bearing from the Drake Field: RWY 34–LOC from the 4.0-mile radius to 4.9 miles south of the Drake Field: RWY 34–LOC; and adding an extension 1.0 mile each side of the 347° bearing from the airport from the 4.0-mile radius to 4.9 miles north the airport. The city associated with the airport would be removed from the airspace legal description to comply with a change to FAA Order 7400.2L, Procedures for Handling Airspace Matters, and the outdated term ''Airport/Facility Directory'' would be updated to ''Chart Supplement.'' Additionally, the geographic coordinates of the airport would be updated to coincide with the FAA's aeronautical database.

Amending the Class E airspace designated as a surface area at Drake Field to within a 4.0-mile radius (decreased from a 4.1-mile radius); and extending the airspace up to and including 3,800 feet MSL; and adding an extension 1.1 miles each side of the 181° bearing from the airport from the 4.0-mile radius to 5.9 miles south of the airport, and adding an extension 1.0 mile each side of the 172° bearing from the Drake Field: RWY 34–LOC from the 4.0-mile radius to 4.9 miles south of the Drake Field: RWY 34–LOC; and adding an extension 1.0 mile each side of the 347° bearing from the airport from the 4.0-mile radius to 4.9 miles north of the airport. The city associated with the airport would be removed from the airspace legal description to comply with a change to FAA Order 7400.2L, Procedures for Handling Airspace Matters, and the outdated term ''Airport/Facility Directory'' would be updated to ''Chart Supplement.'' Additionally, the geographic coordinates of the airport would be updated to coincide with the FAA's aeronautical database.

And removing the Class E airspace designated as an extension to Class D and Class E at Drake Field as it is no longer required.

This action as the result of an airspace review caused by the decommissioning of the Drake VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

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

Paragraph 5000 Class D Airspace.

* * * * *

ASW AR D Fayetteville, AR [Amended]

Drake Field, AR
(Lat. 36°00′18″ N, long. 94°10′12″ W)
Drake Field: RWY 34–LOC
(Lat. 36°00′26″ N, long. 94°10′10″ W)

That airspace extending upward from the surface to and including 3,800 feet MSL within a 4.0-mile radius of Drake Field, and within 1.1 miles each side of the 181° bearing from the airport from the 4.0-mile radius to 5.9 miles south of the airport, and within 1.0 mile each sided of the 172° bearing from the Drake Field: RWY 34–LOC from the 4.0-mile radius to 4.9 miles south of the Drake Field: RWY 34–LOC, and within 1.0 mile each side of the 347° bearing from the airport from the 4.0-mile radius to 4.9 miles north of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ASW AR E2 Fayetteville, AR [Amended]

Drake Field, AR
(Lat. 36°00′18″ N, long. 94°10′12″ W)
Drake Field: RWY 34–LOC
(Lat. 36°00′26″ N, long. 94°10′10″ W)

That airspace extending upward from the surface to and including 3,800 feet MSL within a 4.0-mile radius of Drake Field, and within 1.1 miles each side of the 181° bearing from the airport from the 4.0-mile radius to 5.9 miles south of the airport, and within 1.0 mile each sided of the 172° bearing from the Drake Field: RWY 34–LOC from the 4.0-mile

radius to 4.9 miles south of the Drake Field: RWY 34–LOC, and within 1.0 mile each side of the 347° bearing from the airport from the 4.0-mile radius to 4.9 miles north of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension of Class D and Class E Surface Areas.

* * * * *

ASW OK E4 Fayetteville, AR [Removed]

Issued in Fort Worth, Texas, on September 10, 2018.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2018–20400 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

[NPS–DEVA–25759; PPWONRADE2, PMP00EI05.YP0000]

RIN 1024–AE48

Special Regulations, Areas of the National Park System, Death Valley National Park; Designation of Airstrip

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service proposes to revise the special regulations for Death Valley National Park to designate the Saline Valley Warm Springs Airfield, commonly known as the Chicken Strip, within the Saline Valley Warm Springs area as a location available for the operation of aircraft.

DATES: Comments on the proposed rule must be received by 11:59 p.m. EDT on November 19, 2018.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1024–AE48, by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail to:* Death Valley National Park, P.O. Box 579, Death Valley, CA 92328, Attention: Superintendent.
- *Instructions:* Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions received must include the words ''National Park Service'' or ''NPS'' and must include the docket number or RIN (1024–AE48) for this rulemaking. Comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kelly Daigle, National Park Service, Environmental Quality Division, (303) 987–6897, *kelly_daigle@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

Saline Valley is a large desert valley located in the northwest portion of Death Valley National Park (the park). The Saline Valley Warm Springs area is approximately 1,100 acres of backcountry surrounded by wilderness. This area is distinctive, both in the setting of the site and in its geology. Saline Valley is a closed basin, which means that the water does not flow to another body of water. Water in closed basins only leaves the system by evaporation or diversion. The Saline Valley Warm Springs are among the highest-flow springs in the park. The mountain ranges surrounding this valley, Saline Range, Last Chance Range, and Inyo Range, have elevations ranging from 7,000 feet to over 11,000 feet, which result in spectacular views from the Saline Valley Warm Springs.

The Timbisha Shoshone Tribe (the Tribe), whose homelands encompass the entirety of the park, has a deep affinity for the Saline Valley Warm Springs area due to the existence of long-lived historical and ethnographic connections. The Timbisha Shoshone Homeland Act of 2000 (Homeland Act; Pub. L. 106–423) specified designated special use areas. Saline Valley is part of one of these special use areas. The waters of the warm springs in Saline Valley are a source of *puha* for the Tribe, a life force energy. Although the development of the area by Euro-Americans degraded *puha* and other ethnographic resources, Tribal leaders still seek these cultural connections from historic times until the present and will continue to do so in the future.

The Saline Valley Warm Springs area has not been formally or systematically developed for use by the NPS but does have a number of user-developed and user-maintained structures and facilities. Visitors enjoy backcountry camping and soaking tubs created by diverting water from natural source springs. Visitors use the Saline Valley Warm Springs area throughout the year but the cooler months, October to May, receive the highest use; holidays are times of especially heavy use. The Lower Spring area is the most developed and includes the following features: Cool Pool, Sunrise Pool, Crystal Pool, Children's Play Tub, communal fire pit, library, shower, bathtub, sink for dishwashing, maintained lawn, settling pond, auto shop, and the camp host site. It is the site of many communal activities, such as group fires, communal dinners, and singing. The site contains heavy burro concentration and use, and invasive species such as palm trees and Bermuda grass.

Chicken Strip Airstrip

There is a small, unimproved landing strip to the west of Lower Spring, referred to as the Chicken Strip. The formal name of the airstrip is the Saline Valley Warm Springs Airfield. The airstrip is located at latitude N 36°48.41″, longitude W 117°46.90″. In past years, there were up to three landing strips for small planes in this area. The Suicide Strip and the Crosswinds Strip have been decommissioned. Historically, the landing strips were used by miners and prospectors to access Saline Valley. The Chicken Strip is the only remaining active landing strip within the Saline Valley Warm Springs area. It is approximately 1,400 feet long and 35 feet wide. The strip has a tie-down area large enough to accommodate five small planes. Features of the airstrip include a windsock, painted rocks lining the strip, and two airplane tie-downs. Visitors who fly into the Saline Valley Warm Springs area via the Chicken Strip often camp next to their airplanes.

The Chicken Strip surface is maintained by the community of recreational pilots who use it. The Recreational Aviation Foundation (RAF), an organization of private pilots, is active in the promotion of the continued use of the Chicken Strip. In 2017, the NPS renewed a memorandum of understanding (MOU) with the RAF that allows the RAF to maintain the Chicken Strip at no cost to the NPS. Maintenance activities include leveling the surface, removing stones and debris, and packing the surface.

Based on visitor registration logs at the Chicken Strip, approximately 440 people visited Saline Valley via airplane from 2008 to 2012, averaging 88 visitors per year. Of the aircraft reported, approximately two-thirds were Cessna models. Other types of planes included various models of Pipers, Maules, and Beechcraft. The largest number of people recorded in one aircraft was six.

The Chicken Strip is the last backcountry airstrip remaining in the park and provides a unique and challenging aviation experience. Retaining use of the airstrip would benefit visitor use and experience for those visitors who seek this type of recreation or those visitors who enjoy watching the aircraft fly into the Warm Springs area. For some visitors with injuries or disabilities and who have access to small planes, the Chicken Strip airstrip is the only way they can access the Warm Springs area because the drive is too long and harsh for them.

Proposed Rule

This rule would designate the Chicken Strip airstrip as available for use by aircraft. This action would implement part of the preferred alternative identified in the 2018 Saline Valley Warm Springs Draft Management Plan/Environmental Impact Statement (DEIS). The airstrip has been in use since before the NPS began managing the Saline Valley Warm Springs area in 1994 and this rule would codify the continued use of the airstrip. National Park Service (NPS) regulations at 36 CFR 2.17(a)(1) prohibit the operation or use of an aircraft on lands or waters other than at locations designated pursuant to a special regulation.

This rule would also remove references to ''Death Valley National Monument'' and ''Monument'' in section 2.17 and replace them with references to ''Death Valley National Park'' and ''Park''. This reflects the abolishment of Death Valley National Monument and the establishment of Death Valley National Park in 1994. 16 U.S.C. 410aaaa–1.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this rule in a manner consistent with these requirements.

Reducing Regulation and Controlling Regulatory Costs (Executive Order 13771)

Enabling regulations are considered deregulatory under guidance implementing E.O. 13771 (M–17–21). This rule authorizes the Superintendent to allow a recreational activity for the public to enjoy and experience certain areas within the National Park System that would otherwise be prohibited.

Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This certification is based on information in the report entitled ''Benefit-Cost and Regulatory Flexibility Analyses: Cost-Benefit and Regulatory Flexibility Threshold Analyses: Proposed Special Regulations for Designation of Airstrip at Death Valley National Park'' which is available online at *http://parkplanning.nps.gov/deva* by clicking on the link entitled ''Saline Valley Warm Springs Management Plan EIS'' and then clicking on the link entitled ''Document List.''

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (2 U.S.C. 1531 et seq.)

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. It addresses public use of national park lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act is not required.

Takings (Executive Order 12630)

This rule does not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This proposed rule only affects use of federally-administered lands and waters. It has no outside effects on other areas. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. This rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. The NPS has evaluated this rule under the criteria in Executive Order 13175 and under the Department's tribal consultation policy and has determined that tribal consultation is not required because the rule will not have a substantial direct effect on federally recognized Indian tribes, although consultation under the National Environmental Policy Act and the National Historic Preservation Act was completed. The NPS invited the Tribe to become a cooperating agency on the Draft Management Plan/Environmental Impact Statement (DEIS) on April 3,

2012. The NPS has since conducted formal consultation with the Tribe and invited their participation on issues and alternatives development and internal document review. In addition to formal consultation, the NPS commissioned an assessment of the eligibility of the Saline Valley Warm Springs area as an ethnographic site eligible for listing on the National Register of Historic Places under Criterion A. This assessment was submitted to the State Historic Preservation Office in early 2018.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. The NPS may not conduct or sponsor and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA)

This rule is part of a larger planning process for Saline Valley Warm Springs that constitutes a major Federal action significantly affecting the quality of the human environment. NPS has prepared the DEIS under the NEPA. A copy of the DEIS can be found online at *http://parkplanning.nps.gov/deva,* by clicking on the link entitled ''Saline Valley Warm Springs Management Plan EIS'' and then clicking on the link entitled ''Document List.''

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects in not required.

Clarity of This Rule

The NPS is required by Executive Orders 12866 (section 1(b)(12)) and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule the NPS publishes must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use common, everyday words and clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that the NPS has not met these requirements, send the NPS comments by one of the methods listed in the **ADDRESSES** section. To better help the NPS revise the rule, your comments should be as specific as possible. For example, you should identify the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Participation

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule by one of the methods listed in the **ADDRESSES** section of this document.

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.

List of Subjects in 36 CFR Part 7

District of Columbia, National parks, Reporting and Recordkeeping requirements.

In consideration of the foregoing, the National Park Service proposes to amend 36 CFR part 7 as set forth below:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

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

Authority: 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under DC Code 10–137 and DC Code 50–2201.07.

■ 2. Amend § 7.26 by:

■ a. Revising the section heading.

■ b. In paragraphs (a) and (d), removing the term ''Death Valley National Monument'' and adding in its place ''Death Valley National Park''.

■ c. In paragraphs (b) and (c), removing the term ''Monument'' and adding in its place ''Park''.

■ d. Adding paragraph (e)(3).

The revision and addition to read as follows:

§ 7.26 Death Valley National Park.

* * * * *

(e) * * *

(3) Saline Valley Warm Springs Airfield, latitude N 36°48.41″, longitude W 117°46.90.

Andrea Travnicek,

Principal Deputy Assistant Secretary—Water and Science Exercising the Authority of the Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2018–20332 Filed 9–19–18; 8:45 am]

BILLING CODE 4310–EJ–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 395

[Docket No. FMCSA–2018–0248]

RIN 2126–AC19

Hours of Service

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Announcement of public listening session.

SUMMARY: The FMCSA announces that it will hold a public listening session concerning potential changes to its hours-of-service (HOS) rules for truck drivers. On August 23, 2018, FMCSA published an Advance Notice of Proposed Rulemaking (ANPRM) seeking public comment on four specific aspects of the HOS rules for which the Agency is considering changes: the short-haul HOS limit; the HOS exception for adverse driving conditions; the 30-minute rest break provision; and the sleeper berth rule to allow drivers to split their required time in the sleeper berth. In addition, the Agency requested public comment on petitions for rulemaking from the Owner-Operator Independent Drivers Association (OOIDA) and TruckerNation.org (TruckerNation). The Agency encourages vendors of electronic logging devices (ELDs) to participate to address potential implementation issues should changes to the HOS rules be made. The listening session is the third in a series and will be held at the National Automobile Museum in Reno, NV. The listening session will be webcast for the benefit of those not able to attend in person. The listening session will allow interested persons to present comments, views, and relevant research on topics mentioned above. All comments will be transcribed and placed in the rulemaking docket for the FMCSA's consideration.

DATES: The listening session will be Saturday, September 22, 2018, in Reno, NV.

ADDRESSES: The September 22, 2018, meeting will be held at the National Automobile Museum, 10 S. Lake Street, Reno, NV 89501. The listening session will begin at 10 a.m. (PDT) and end at 12 noon, or earlier, if all participants wishing to express their views have done so.

You may submit comments identified by Docket Number FMCSA-2018-0248 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.
- *Submissions Containing Confidential Business Information (CBI)*: Mr. Brian Dahlin, Chief, Regulatory Analysis Division, 1200 New Jersey Avenue SE, Washington, DC 20590.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments, including collection of information comments for the Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: For special accommodations for the HOS listening session, such as sign language interpretation, contact Mr. William Cunnane, Program Specialist, at (202) 366–0055 or *william.cunnane@dot.gov,* by Monday, September 17, 2018, to allow us to arrange for such services. There is no guarantee that interpreter services requested on short notice can be provided. For information concerning the HOS rules, contact Mr. Tom Yager, Chief, Driver and Carrier Operations Division, (202) 366–4325, *mcpsd@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this ANPRM (Docket No. FMCSA–2018-0248), indicate the specific section of this document to which each section applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2018–0248, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period for the ANPRM. Late comments will be considered to the extent practicable.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is customarily not made available to the public by the submitter. Under the Freedom of Information Act, CBI is eligible for protection from public disclosure. If you have CBI that is relevant or responsive to the ANPRM and this listening session, it is important that you clearly designate the submitted comments as CBI. Accordingly, please mark each page of your submission as ''confidential'' or ''CBI.'' Submissions designated as CBI and meeting the definition noted above will not be placed in the public docket for the ANPRM and this listening session. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Analysis Division, 1200 New Jersey Avenue SE, Washington, DC 20590 or *brian.dahlin@dot.gov.* Any commentary that FMCSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

FMCSA will consider all comments and material received during the comment period for the ANPRM.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0248, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On August 23, 2018 (83 FR 42631), FMCSA published an ANPRM concerning potential changes to its hours-of-service rules. The ANPRM indicated the Agency is considering changes in four areas of the HOS rules: The short-haul HOS limit [49 CFR 395.1(e)(1)(ii)(A)]; the HOS exception for adverse driving conditions [§ 395.1(b)(1)]; the 30-minute rest break provision [§ 395.3(a)(3)(ii)]; and the sleeper berth rule to allow drivers to split their required time in the sleeper berth [§ 395.1(g)(1)(i)(A) and (ii)(A)]. In addition, the Agency requested public comment on petitions for rulemaking from the Owner-Operator Independent Drivers Association (OOIDA) and TruckerNation.org (TruckerNation). The ANPRM provides an opportunity for additional discussion of each of these topics. The listening session will provide interested persons to share their views on these topics with representatives of the Agency. The Agency encourages ELD vendors to participate to address potential implementation issues should changes to the HOS rules be made.

III. Meeting Participation

The listening session is open to the public. Speakers' remarks will be limited to 2 minutes each. The public may submit material to the FMCSA staff at the session for inclusion in the public docket, FMCSA–2018–0248. The

session will be webcast in its entirety, providing the opportunity for remote participation via the internet. For information on participating in the live webcast, please go to *www.fmcsa.dot.gov.*

IV. Questions for Discussion During the Listening Session

In preparing their comments, meeting participants should consider the questions posed in the ANPRM about the current HOS requirements. Answers to these questions should be based upon the experience of the participants and any data or information they can share with FMCSA.

Issued on: September 14, 2018.

Cathy F. Gautreaux,

Deputy Administrator.

[FR Doc. 2018–20427 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 395

[Docket No. FMCSA–2018–0248]

RIN 2126–AC19

Hours of Service of Drivers

ACTION: Advance notice of proposed rulemaking (ANPRM); Extension of comment period.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) extends the comment period for its August 23, 2018, ANPRM concerning hours of service for drivers of property-carrying commercial motor vehicles (CMVs). FMCSA received requests for an extension to the comment period from a number of organizations, including the American Trucking Association, the Commercial Vehicle Safety Alliance, the International Brotherhood of Teamsters, the National Pork Producers Council, and the National Tank Truck Carriers, Inc. The Agency believes it is appropriate to extend the comment period to provide interested parties additional time to submit their responses to the ANPRM. Therefore, the Agency extends the deadline for the submission of comments from September 24, 2018, to October 10, 2018.

DATES: The comment period for the ANPRM published August 23, 2018 at 83 FR 42631 is extended. Comments on the ANPRM must be received on or before October 10, 2018.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2018–0248 using any one of the following methods:

Federal Rulemaking Portal: www.regulations.gov. Follow the online instructions for submitting comments.

Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

Fax: 202–493–2251.

Hand Delivery or Courier: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Submissions Containing Confidential Business Information (CBI): Mr. Brian Dahlin, Chief, Regulatory Evaluation Division, 1200 New Jersey Ave. SE, Washington, DC 20590.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' heading under the **SUPPLEMENTARY INFORMATION** section below for instructions regarding submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Yager, Chief, Driver and Carrier Operations Division, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, at (202) 366–4325, or via email: *mcpsd@dot.gov.*

If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2018–0284), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and enter either docket number, ''FMCSA–2018–0284'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this proposed rule based on your comments. Late comments will be considered to the extent practicable.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is customarily not made available to the general public by the submitted. Under the Freedom of Information Act, CBI is eligible for protection from public disclosure. If you have CVI that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Accordingly, please mark each page of your submission as ''confidential'' or ''CBI.'' Submissions designated as CBI and meeting the definition noted above will not be placed in the public docket. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, 1200 New Jersey Ave. SE, Washington, DC 20590. Any commentary that FMCSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Viewing Comments and Documents

To view comments, as well as documents available in the docket, go to *http://www.regulations.gov* and insert the docket number, ''FMCSA–2018–0248'' in the ''Keyword'' box and click ''Search.'' Next, click ''Open Docket Folder'' button and choose the document listed to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey

Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Privacy Act

Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its potential rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Background

The August 23, 2018 ANPRM (83 FR 42631) asked for public comment on four subject areas: Short haul operations, adverse conditions, the 30-minute break, and the split-sleeper berth provision. The ANPRM also sought public comment on two petitions for rulemaking from the Owner-Operator Independent Drivers Association (OOIDA) and TruckerNation.

FMCSA held a public listening session on August 24, 2018, at the Great American Truck Show, in Dallas, Texas (83 FR 42630).

Extension of the Public Comment Period

The comment period for the ANPRM was set to expire on September 24, 2018 (83 FR 42631). FMCSA received several requests to extend the comment period, as noted above. Copies of the requests are included in the docket referenced at the beginning of this notice.

The organizations requested various lengths of time for the extension ranging from 30 to 60 days, stating that the additional time was needed to enable them to prepare more comprehensive responses based on research and information that has only recently been released or is expected to be released at upcoming industry meetings.

FMCSA has determined that extending the comment period would provide the organizations additional time to prepare more detailed comments that are reflective of the concerns of their members. Accordingly, FMCSA extends the comment period for all comments on the ANPRM to October 10, 2018.

Issued under the authority of delegations in 49 CFR 1.87: September 14, 2018.

Cathy F. Gautreaux,

Deputy Administrator.

[FR Doc. 2018–20430 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 180503449–8782–01]

RIN 0648–XG232

Endangered and Threatened Wildlife; Positive 90-Day Finding on a Petition To List the Cauliflower Coral, Pocillopora Meandrina, in Hawaii as Endangered or Threatened Under the Endangered Species Act

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

ACTION: 90-day petition finding, request for information, and initiation of status review.

SUMMARY: We, NMFS, announce a 90-day finding on a petition to list the cauliflower coral (*Pocillopora meandrina)* in Hawaii as an endangered or threatened species under the Endangered Species Act (ESA). The petition requested that the Hawaii population of *P. meandrina* be considered a significant portion of the range of the species, and that the species be listed because of its status in Hawaii. Our policy on the interpretation of the phrase ''Significant Portion of Its Range'' (SPR) under the ESA states that, before undergoing an SPR analysis, we must first find that the species is neither endangered nor threatened throughout all of its range. Therefore, we interpret the petition as a request to consider the status of *P. meandrina* throughout its range first. We find that the petition and other readily available information in our files indicates that *P. meandrina* may warrant listing as a threatened species or an endangered species throughout its range. Thus, we will initiate a global status review of *P. meandrina* to determine whether listing it throughout its range is warranted. If not, we will determine if Hawaii constitutes an SPR, and proceed accordingly. To ensure that the status review is comprehensive, we are soliciting scientific and commercial information pertaining to *P. meandrina* from any interested party.

DATES: Information and comments on the subject action must be received by November 19, 2018.

ADDRESSES: You may submit comments, information, or data on this document, identified by the code NOAA–NMFS–2018–0060, by either of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0060.* Click the ''Comment Now'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Lance Smith, NOAA IRC, NMFS/PIRO/PRD, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *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 petition and related materials are available on our website at *http://www.fisheries.noaa.gov/species/Pocillopora-meandrina.*

FOR FURTHER INFORMATION CONTACT: Lance Smith, NMFS, Pacific Islands Regional Office, Protected Resources Division, (808) 725–5131; or Chelsey Young, NMFS, Office of Protected Resources, 301–427–8403.

SUPPLEMENTARY INFORMATION:

Background

On March 14, 2018, we received a petition from the Center for Biological Diversity to list the cauliflower coral (*Pocillopora meandrina*) in Hawaii as an endangered or threatened species under the ESA. The petition asserts that *P. meandrina* in Hawaii is threatened by at least four of the five ESA section 4(a)(1) factors: (1) Pesent modification of its habitat; (2) disease and predation; (3) inadequacy of existing regulatory mechanisms: and (4) other natural or manmade factors, specifically ocean warming and ocean acidification resulting from global climate change. Copies of the petition are available upon request (see **ADDRESSES**).

ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary

of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). When it is found that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a ''positive 90-day finding''), we are required to commence a comprehensive review of the status of the species concerned using the best available scientific and commercial information, which we will conclude with a finding as to whether, in fact, the petitioned action is warranted. This finding is due within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the available information, compared to the narrow scope of review at the 90-day stage, a ''may be warranted'' 90-day finding does not prejudge the outcome of the 12-month finding.

ESA-implementing regulations issued jointly by NMFS and USFWS (50 CFR 424.14(h)(1)(i)) define ''substantial scientific or commercial information'' in the context of reviewing a petition to list, delist, or reclassify a species as credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted. Conclusions drawn in the petition without the support of credible scientific or commercial information will not be considered ''substantial information.'' In evaluating whether substantial information is contained in the petition, we consider whether the petition (1) Clearly indicates the administrative measure recommended and gives the scientific and any common name of the species involved; (2) contains a detailed narrative justification for the recommended measure, describing, based on available information, past and present numbers and distribution of the species involved and any threats faced by the species; (3) provides information regarding the status of the species over all or a significant portion of its range; and (4) is accompanied by the appropriate supporting documentation in the form of bibliographic references, reprints of pertinent publications, copies of reports or letters from authorities, and maps (50 CFR 424.14(b)(2)).

Under the ESA, a listing determination addresses the status of a species, which is defined to also include subspecies and, for any vertebrate species, any distinct population segment (DPS) that interbreeds when mature (16 U.S.C. 1532(16)). Because *P. meandrina* is an invertebrate, it cannot qualify as a DPS. Under the ESA, a species is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range, or ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). The petition requests that the Hawaii portion of the species' range be considered a significant portion of its range, thus the petition focuses primarily on the status of *P. meandrina* in Hawaii. However, the petition also requests that *P. meandrina* be listed throughout its range, and provides some information on its status and threats outside of Hawaii. Our policy on the interpretation of the phrase ''significant portion of its range'' (SPR) under the ESA (79 FR 37577, July 1, 2014) states that, before undergoing an analysis of SPR, we must first find that the species is neither endangered nor threatened throughout all of its range. Therefore, we interpret the petition as a request to consider the status of *P. meandrina* throughout its range first; and if appropriate, subsequently consider whether *P. meandrina* in Hawaii constitutes an SPR and the status of that SPR.

At the 90-day finding stage, we evaluate the petitioners' request based upon the information in the petition including its references and the information readily available in our files. We do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We are not required to consider any supporting materials cited by the petitioner if the petitioner does not provide electronic or hard copies, to the extent permitted by U.S. copyright law, or appropriate excerpts or quotations from those materials (*e.g.,* publications, maps, reports, and letters from authorities). We will accept the petitioners' sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition's information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person would conclude it supports the petitioners' assertions. In other words, conclusive information indicating the species may meet the ESA's requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone negates a positive 90-day finding if a reasonable person would conclude that the unknown information itself suggests an extinction risk of concern for the species at issue. See 50 CFR 424.14 for regulations on petitions under the ESA.

Our determination as to whether the petition provides substantial scientific or commercial information indicating that the petitioned action may be warranted depends in part on the degree to which the petition includes the following types of information: (1) Information on current population status and trends and estimates of current population sizes and distributions, both in captivity and the wild, if available; (2) identification of the factors under section 4(a)(1) of the ESA that may affect the species and where these factors are acting upon the species; (3) whether and to what extent any or all of the factors alone or in combination identified in section 4(a)(1) of the ESA may cause the species to be an endangered species or threatened species (*i.e.,* the species is currently in danger of extinction or is likely to become so within the foreseeable future), and, if so, how high in magnitude and how imminent the threats to the species and its habitat are; (4) information on adequacy of regulatory protections and effectiveness of conservation activities by States as well as other parties, that have been initiated or that are ongoing, that may protect the species or its habitat; and (5) a complete, balanced representation of the relevant facts, including information that may contradict claims in the petition. See 50 CFR 424.14(d).

The factors under section 4(a)(1) of the ESA that may affect the species are as follows: (1) The present or threatened destruction, modification, or curtailment of habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms to address identified threats; rand (5) any other natural or manmade factors affecting the species' existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)). Information presented on these factors should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act or have acted on the species to the point that it may

warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, do not constitute substantial information indicating that listing may be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion; then we assess the potential significance of that negative response.

Taxonomy of the Petitioned *P. meandrina*

As described in the final rule to list 20 species of coral under the ESA (79 FR 53851; September 10, 2014), the morphology-based taxonomy of the genus *Pocillopora,* including *P. meandrina,* has been called into question by several recent genetics papers. A range-wide phylogeographic survey that included most currently recognized pocilloporid species found that reliance on colony morphology is broadly unreliable for species identification, and that several genetic groups have highly limited geographic distributions. The study concluded that ''a taxonomic revision informed foremost by genetic evidence is needed for the entire genus'' (Pinzo 301;n *et al.,* 2013). Similarly, a phylogeographic survey of several currently recognized pocilloporid species representing a range of atypical morphologies thought to be rare or endemic to remote locations throughout the Indo-Pacific found that (1) the current taxonomy of *Pocillopora* based on colony morphology shows little correspondence with genetic groups; (2) colony morphology is far more variable than previously thought; and (3) there are numerous cryptic lineages (*i.e.,* two or more distinct lineages that are classified as one due to morphological similarities). The study concluded that ''the genus *Pocillopora* is in need of taxonomic revision using a combination of genetic, microscopic characters, and reproductive data to accurately delineate species'' (Marti-Puig *et al.,* 2014). Likewise, a more limited study of several currently recognized pocilloporid species in Moorea, French Polynesia found that genetic groups do not correspond to colony morphology, and exhibit a wide range of morphological variation (Forsman *et al.,* 2013).

These studies demonstrate that colony morphology in pocilloporids is a poor indicator of taxonomic relationships for the following reasons: (1) Morphologically similar colonies may not be the same species (*i.e.,* colonies of different species appear similar because of similar environmental conditions or other reasons); and (2) morphologically different colonies may be the same species (*i.e.,* colonies of the same species appear different because of different environmental conditions or other reasons). Because of the taxonomic uncertainty for the genus *Pocillopora,* we concluded in the final listing rule that no final listing decision could be made for the two *Pocillopora* species that had been proposed for listing in 2012 (*P. elegans, P. danae;* 79 FR 53851; September 10, 2014).

Other recent papers on genetic or morphological aspects of *Pocillopora* taxonomy that were in our files when we received the petition (Johnston *et al.,* 2017; Johnston *et al.,* 2018; Pas-Garcia *et al.,* 2015; Schmidt-Roach *et al.,* 2014) indicate that gross morphological plasticity is characteristic of *Pocillopora* species, thus morphological data should be supplemented with genetic data for accurate identification of species (Johnston *et al.,* 2017). A combined genetics and morphology study of several *Pocillopora* species, including *P. meandrina,* did not propose any taxonomic changes to *P. meandrina.* The study found that, in contrast to morphological similarities, *P. verrucosa* and *P. meandrina* are very distinct genetically, and *P. meandrina* is much more closely related to *P.eydouxi* than to *P. verrucosa* genetically (Schmidt-Roach *et al.,* 2014). The morphological plasticity of *Pocillopora* species was shown by a study of *P. damicornis* and *P. inflata* at a site in the southern Gulf of California that coincided with a shift to a higher frequency of storms and lower water turbidity. Over the 44-month period of the study, 23 percent of the *P. damicornis* colonies changed shape to *P. inflata* morphology, providing an *in situ* demonstration of the influence of temporal shifts in environmental conditions on morphologically plastic responses (Pas-Garcia *et al.,* 2015). A genomic study found that *Pocillopora* species are genetically distinct from one another, and that there is a lack of introgressive hybridization between species. Some of these authors went on to develop a genetic technique for identification of Hawaiian *Pocillopora* species, and found that morphology-based identifications often led to *P. ligulata* being mistaken for *P. meandrina* (Johnston *et al.,* 2018).

Despite doubt raised by traditional morphology-based taxonomy, other readily available information in our files presents substantial scientific or commercial information indicating that *P. meandrina* may constitute a valid species for the following reasons: (1) The recent taxonomic revision to some *Pocillopora* species did not propose any changes to *P. meandrina* (Schmidt-Roach *et al.,* 2014); (2) other recent papers have found that *Pocillopora* species, including *P. meandrina,* are genetically distinct from one another (Johnston *et al.,* 2017, 2018), and; (3) the growing genetic information on *P. meandrina* could lead to the description of sub-species rather than new species, but sub-species are treated as species under the ESA. Therefore, *P. meandrina* may be a type of entity that is eligible for listing under the ESA.

Habitat, Range, and Life History

Pocillopora meandrina occurs on shallow reefs and amongst coral communities on rocky reefs at depths of 1 to 27m, and is common in high-energy reef front environments (shallow forereef) throughout its range (Fenner, 2005; Hoeksma *et al.,* 2014; Veron, 2000). In Hawaii and the eastern Pacific, *P. meandrina* is often the dominant species in shallow forereef coral communities (Fenner, 2005; Glynn, 2001). It is found on most coral reefs of the Indo-Pacific and eastern Pacific, with its range encompassing over 180° longitude from the western Indian Ocean to the eastern Pacific Ocean, and approximately 60° latitude from the northern Ryukyu Islands to central western Australia in the western Pacific, and the Gulf of California to Easter Island in the eastern Pacific (Corals of the World website *http://www.coralsoftheworld.org/*).

Pocillopora meandrina has a branching colony morphology, is a broadcast spawner, and has rapid skeletal growth, allowing it to recruit quickly to available substrate and successfully compete for space (Darling *et al,* 2012). High recruitment rates, rapid skeletal growth, and successful competition are well documented for *P. meandrina* in Hawaii (*e.g.,* Brown, 2004; Grigg and Maragos, 1974) and the eastern Pacific (*e.g.,* Jimeénez and Corteés, 2003).

While such competitive reef coral species typically dominate ideal environments, they also have higher susceptibility to threats such as elevated seawater temperatures than reef coral species with generalist, weedy, or stress-tolerant life histories (Darling *et al.,* 2012). For example, *P. meandrina* was among the most affected reef coral species in the 2014 and 2015 mass bleaching events in Hawaii (Kramer *et al.,* 2016; Rodgers *et al.,* 2017). That said, the life history characteristics of *P. meandrina* provide some buffering against threats such as warming-induced bleaching by allowing for rapid

recovery from die-offs. For example, in 2016, *P. meandrina* populations in the main Hawaiian Islands were already showing signs of recovery from the 2014 and 2015 bleaching mortality (PIFSC, unpublished data).

The species has several other characteristics that may also provide buffering against some threats, including the capacity for acclimatization and adaptation to changing conditions, the potential for range expansion as previously unsuitable habitat becomes suitable, and a broad range that encompasses extensive habitat heterogeneity. The bleaching and mortality of some colonies of a coral species on a reef, followed by the recovery of hardier colonies, is the process by which acclimatization and adaptation of a species to ocean warming occurs, and has been documented in some *Pocillopora* species (*e.g.,* Rodríguez-Troncoso, *et al.,* 2010; Coles *et al.,* 2018). As conditions change in response to ocean warming, some areas that were previously too cold for reef corals may become suitable, potentially allowing range expansion of certain species into these areas (Yamano *et al.,* 2011; Yara *et al.,* 2011). Finally, habitat conditions are highly heterogeneous across the ranges of broadly-distributed reef corals such as *P. meandrina,* creating a patchwork of conditions that may potentially provide refugia to threats (Fine *et al.,* 2013; McClanahan *et al.,* 2011).

Abundance and Population Trends

Although there is little species-specific, range-wide data on *P. meandrina*'s abundance and population trends, there are some data available on the species' abundance and population trends in the main Hawaiian Islands portion of the Hawaiian archipelago, which indicate a significant decrease in coral cover over a recent 14-year period, followed by severe bleaching events. The Hawaii Coral Reef Assessment and Monitoring Program (CRAMP) monitors species-level live coral cover at 60 permanent stations throughout the main Hawaiian Islands. From 1999 to 2012, *P. meandrina* decreased in live coral cover by 36.1 percent for all stations combined (Rodgers *et al.,* 2015). Subsequently, *P. meandrina* was severely impacted in parts of the Hawaiian archipelago due to back-to-back warming-induced bleaching events in 2014 and 2015. Surveys of the impacts of these bleaching events on *P. meandrina* in the northwestern and main Hawaiian Islands show high levels of bleaching and post-bleaching mortality in some locations (Couch *et al.,* 2017; Kramer *et al.,* 2016; Rodgers *et al.,* 2017; see ''Other Natural or Manmade Factors—Ocean Warming'' section below). While there are currently no estimates available of the total abundance or overall population trends for *P. meandrina* in the main Hawaiian Islands, the above information strongly indicates that the species has been in decline in this area, and that the decline was accelerated by the back-to-back mass bleaching events of 2014 and 2015.

It is likely that *P. meandrina* has declined in abundance across most, if not all, of its range, over the past 50 to 100 years, and that the decline has recently accelerated. For most of the world's reef corals, Carpenter *et al.* (2008; Supplementary Information) extrapolated species abundance trend estimates from total live coral cover trends (*i.e.,* all reef coral species combined) and habitat types. For *P. meandrina,* the overall decline in abundance was estimated at 22 percent over the 30-year period up to 2006 (''Percent Population Reduction''), and 10 percent over the 30 year period up to the 1998 bleaching event (''Back-cast Percent Population Reduction''). However, total live coral cover trends are highly variable both spatially and temporally, thus data from the same location and time period can be interpreted differently (Bellwood *et al.,* 2004; Sweatman *et al.,* 2011), and species trends do not necessarily correlate with overall live coral cover trends. Thus, quantitative inferences of species-specific trends from total live coral cover trends should be interpreted with caution. At the same time, an extensive body of literature documents global declines in live coral cover, accompanied by shifts to coral reef communities dominated by hardier coral species or algae over the past 50 to 100 years (*e.g.,* Birkeland, 2004; Brainard *et al.,* 2011; Pandolfi *et al.,* 2003; Sale and Szmant, 2012; Veron *et al.,* 2009). Recently, these changes have accelerated in response to an unprecedented series of mass bleaching events across the majority of the world's coral reefs (Hoegh-Guldberg *et al.,* 2017; Hughes 2018a, 2018b; Lough *et al.,* 2018), 90 percent of which are in the Indo-Pacific. Given that *P. meandrina* occurs in many areas affected by these broad changes, and it is susceptible to both global and local threats, the species likely declined in abundance over the past 50 to 100 years across most, if not all, of its range, and that the decline has recently accelerated; but, a precise quantification is not possible based on the limited species-specific information.

Analysis of ESA Section 4(a)(1) Factors

Although the petition presents information on at least four of the five ESA factors in section 4(a)(1) of the ESA (*e.g.,* present modification of its habitat; disease and predation; inadequacy of regulatory mechanisms; and other natural or manmade factors), the information presented in the petition, together with other readily available information in our files, regarding ocean warming (Factor E) is substantial enough to make a determination that a reasonable person conducting an impartial scientific review could conclude that this species may warrant listing as endangered or threatened based on this factor alone. As such, we focus our discussion below on ocean warming and subsequent warming-induced coral bleaching and mortality, and present our evaluation of the information regarding this factor alone and its impact on the extinction risk of the species. However, we note that in the status review for this species, we will evaluate all ESA section 4(a)(1) factors to determine whether any one or a combination of these factors are causing declines in the species or likely to substantially negatively affect the species such that that *P. meandrina* is either presently at risk of extinction or likely to become so in the foreseeable future.

Other Natural or Manmade Factors—Ocean Warming

Information presented in the petition and other readily available information in our files indicate that the most important threat to *P. meandrina* across its range currently and in the future, and to the Indo-Pacific reef coral communities of which *P. meandrina* is a part, is ocean warming and subsequent warming-induced coral bleaching and mortality. Based on this information, we provide summaries of the (1) observed ocean warming to date; (2) projected ocean warming; (3) observed effects of warming-induced mass bleaching on Indo-Pacific reef coral communities and *P. meandrina* to date; and (4) projected effects of warming-induced mass bleaching on Indo-Pacific reef coral communities and *P. meandrina.*

(1) *Observed Ocean Warming.* As described in the 2014 final rule listing 20 reef coral species as threatened (79 FR 53851; September 10, 2014), we considered the International Panel on Climate Change's (IPCC) Fifth Assessment Report (AR5) ''Climate Change 2013: The Physical Science Basis'' (IPCC, 2013) to be the best available information on the physical basis of ocean warming as well as future

projections. Thus the following section is based largely on IPCC (2013), supplemented by more recent information. Since the Industrial Revolution in the mid-19th century, the magnitude and pace of greenhouse gases emissions (GHGs; *e.g.,* carbon dioxide (CO_2) and methane) have rapidly increased, resulting in steadily higher atmospheric GHG concentrations, the most influential of which is CO_2. The IPCC found that these changes have resulted in warming of the global climate system since the 1950s due to trapping of the sun's heat in the atmosphere by the GHGs (*i.e.,* the greenhouse effect). With regard to global ocean warming that has already occurred, the IPCC determined that the upper ocean (0 − 700 m) warmed from 1971 to 2010, including warming of the upper 75 m by 0.11°C per decade. Warming varied regionally among the oceans, but all oceans warmed between 1971 and 2010, including the tropical and sub-tropical Indo-Pacific (IPCC, 2013).

IPCC (2013) was based on data collected through 2010, but overall global warming (oceans and land combined) and ocean warming have both continued at an even greater pace since then. Global temperatures (ocean and land combined) in 2015 and 2016 were the warmest since instrumental record keeping began in the 19th century (NASA, 2016). Ocean warming has continued, and there was more ocean warming in 2014–2016 than any previous three-year period on record (Jewett and Romanou, 2017). There is consensus among several different methods of monitoring seawater temperatures that ocean warming has continued unabated since 2010 both globally and regionally in all of the world's oceans (Gleckler *et al.,* 2016; Cheng *et al.,* 2017; Wang *et al.,* 2018). Between 1998 and 2015, the greatest warming was recorded in the Southern Ocean, the tropical/subtropical Pacific Ocean, and the tropical/subtropical Atlantic Ocean (Cheng, *et al.,* 2017).

(2) *Projected Ocean Warming.* IPCC's AR5 uses projected changes in the global climate system to model potential patterns of future climate based on a set of four Representative Concentration Pathways (RCPs) that provide a standard framework for consistently modeling future climate change. The RCP system is based on levels of positive ''radiative forcing,'' defined as the net energy gain relative to the 1986–2005 average by the year 2100 in terms of watts per square meter (W/m^2); thus, higher values equate to greater warming over the time period. The four pathways are named RCP2.6, RCP4.5, RCP6.0, and RCP8.5 (*e.g.,* RCP2.6 = 2.6 W/m^2 in 2100). The four pathways have atmospheric CO_2 equivalents of 421 (RCP2.6), 538 (RCP4.5), 670 (RCP6.0), and 936 ppm (RCP 8.5) in 2100, and follow very different trajectories to reach those endpoints. Mean global warming estimates by 2100 for the pathways are 1.0°C (RCP2.6), 1.8°C (RCP4.5), 2.2°C (RCP6.0), and 3.7°C (RCP8.5). The four new pathways were developed with the intent of providing a wide range of total climate forcing to guide policy discussions and specifically include one mitigation pathway leading to a very low forcing level (RCP2.6), two stabilization pathways (RCP4.5 and RCP6), and one pathway with continued high GHG emissions (RCP8.5; IPCC, 2013).

The climate change projections, including for ocean warming, ocean acidification, and sea level rise, in the 2014 coral final listing rule were based on RCP8.5 in IPCC's AR5 (IPCC, 2013). RCP8.5 assumes a continued *status quo* increase in global GHG emissions over the 21st century. The NMFS 2014 rule for 20 reef-building corals used RCP8.5 as its basis. Indeed, global energy-related CO_2 emissions grew by approximately 10 percent, with seven of those 10 years setting new historic highs (IEA, 2018); and global atmospheric CO_2 concentration grew from 385 to 407 parts per million, with each year setting new historic highs, according to NOAA's Earth System Research Laboratory station on Mauna Kea, Hawaii (*https://www.esrl.noaa.gov/gmd/ccgg/trends/*). Thus, the best available current information continues to support the NMFS policy that RCP8.5 is the most likely pathway in the future.

RCP8.5 projects that global annual mean ocean surface temperatures will increase from 2013 levels by approximately 0.4–1.0°C by 2030, approximately 0.7–2.0°C by 2060, and approximately 2.0–5.0°C by 2100, further exacerbating the impacts of ocean warming on corals and coral reefs. In the Indo-Pacific, projected changes in annual median ocean surface temperatures under RCP8.5 will increase from 2013 levels by approximately 0.0–1.0°C by 2035, 1.0–3.0°C by 2065, and 2.0–5.0°C by 2100. Spatial variability in the projections consists mostly of larger increases in the Red Sea, Persian Gulf, and the Coral Triangle, and lower increases in the central and eastern Indian Ocean and south-central Pacific. The percent ranges in the projections described above are for the 25 to 75 percent range confidence intervals, however the range of projections within the 5 to 95 percent range confidence intervals are considerably greater (IPCC, 2013). As described in detail in the RCP8.5 Projections section of the 2014 coral final listing rule, these global mean projections are not necessarily representative of ocean surface temperature conditions throughout the ranges and habitats of reef corals in the future, due both to spatial variability and to statistical range of the RCP8.5 ocean warming projections (79 FR 53851; September 10, 2014).

(3) *Observed Effects of Warming-induced Mass Coral Bleaching.* The frequency, intensity, and magnitude of mass coral bleaching events has rapidly increased since the early 1980s, suggesting that tropical coral reef systems are transitioning to a new era in which the interval between recurrent bouts of coral bleaching is too short for a full recovery of mature assemblages (Hughes *et al.,* 2018b).

Warming-induced coral bleaching occurs when elevated seawater temperatures cause the expulsion of the host coral's symbiotic zooxanthellae in response to thermal stress. While mild to moderate bleaching does not necessary cause coral mortality, repeated or prolonged bleaching can lead to colony mortality. Many coral physiological processes are optimized to the local long-term seasonal and interannual variations in seawater temperature experienced by the corals, and an increase of only 1°C–2°C above the normal local seasonal maximum can induce bleaching. Bleaching is best predicted by using an index of accumulated thermal stress above a locally established threshold (Brainard *et al.,* 2011). Most coral species are susceptible to bleaching, but this susceptibility varies among taxa. In addition, many coral species exhibit various levels of adaptation or acclimatization to elevated seawater temperatures. While coral bleaching patterns are complex, there is general agreement that thermal stress has led to accelerated bleaching and mass mortality during the past several decades. During the years 1983, 1987, 1995, 1996, 1998, 2002, 2004, 2005, 2014, 2015, and 2016, widespread warming-induced coral bleaching and mortality was documented in many reef coral communities that *P. meandrina* is part of in the Indo-Pacific and the eastern Pacific (Jokiel and Brown, 2004; Kenyon and Brainard, 2006; Brainard *et al.,* 2011; Rodgers *et al.,* 2017; Hughes *et al.,* 2017a, 2018a). The bleachings of 2014–2016 were the longest, most widespread, and likely the most damaging coral bleaching events on record. They affected more coral reefs than any previous global bleaching

event, and were worse in some locales than ever recorded before (*e.g.,* Great Barrier Reef/GBR, Kiribati, Jarvis Island). Heat stress during this event also caused mass bleaching in several reefs where bleaching had never been recorded before (*e.g.,* northernmost GBR; Eakin, 2017).

According to the information in the petition and other readily available information in our files, warming-induced bleaching and mortality have impacted *P. meandrina,* including in the Hawaiian archipelago and the GBR. In Hawaii, *P. meandrina* is one of the most common coral species and often dominates the forereef coral community. The consecutive bleaching events of 2014 and 2015 in the Hawaiian archipelago were unprecedented in scale, intensity, and magnitude, and *P. meandrina* was one of the most severely affected reef coral species (Couch *et al.,* 2017; Rodgers *et al.,* 2017). Surveys in late 2014 at multiple sites on four islands in the northwestern Hawaiian Islands showed 15.5 percent of *P. meandrina* colonies had been bleached (colonies that lost >50% of pigmentation). Surveys were repeated in 2015 for post-bleaching mortality of coral species making up >1 percent of live coral at the 2014 survey sites. Only one site had >1 percent of *P. meandrina* in 2014, and that site had no *P. meandrina* in 2015 (Couch *et al.,* 2017). Surveys of eight sites in Hanauma Bay on Oahu in 2015 and 2016 found that 64 percent of *P. meandrina* colonies showed ''signs of bleaching'', and that 1.3 percent of the *P. meandrina* colonies suffered total post-bleaching mortality (Rodgers *et al.,* 2017). Surveys at eight permanent monitoring sites on the west coast of the Big Island of Hawaii in 2015 showed a mean loss in live coral cover (all species combined) of 49.6 percent. Surveys of the seven sites where *P. meandrina* had been abundant before the bleaching events showed that 77.6 percent of the *P. meandrina* colonies suffered total post-bleaching mortality (Kramer *et al.,* 2016).

The 2016 warming-induced bleaching event across the Indo-Pacific was the worst in recorded history in terms of severity and duration of elevated seawater temperatures and ensuing mass coral bleaching and mortality (Lough *et al.,* 2018). Much of the GBR was affected by the elevated seawater temperatures, resulting in bleaching levels of 75–100 percent on many of the GBR's northern reefs, and a mean reduction in live coral cover of 30 percent across the entire 2,300 km GBR between March and November 2016. In March and April 2016, a survey was conducted on 83 reefs spanning the central and northern GBR to determine the responses of 31 reef coral taxonomic groups to the bleaching event, including ''other *Pocillopora*'' (*P. meandrina* and *P. verrucosa*). This group was the third-most bleached of the 31 groups. A sub-sample of 43 of the most affected reefs was re-surveyed in November 2016 to determine the extent of post-bleaching mortality and subsequent loss of live coral cover, which showed that the ''other *Pocillopora*'' group had approximately 55 percent loss of live coral cover (Hughes *et al.,* 2017a, 2018a).

Although difficulty in identification of *Pocillopora* species and lack of species-level field surveys means little of the available information on the impacts of warming-induced bleaching on *Pocillopora* species is specifically for *P. meandrina,* the family Pocilloporidae and the genus *Pocillopora* are highly susceptible to warming-induced bleaching relative to other reef corals. A survey of the susceptibilities of 40 reef coral taxa to the 1998 warming-induced mass bleaching event on the GBR found that three Pocilloporidae species (*P. damicornis, Stylophora pistillata, Seriatopora hysrix*) were among the seven most susceptible taxa (Marshal and Baird, 2000). Similarly, a survey of the sensitivities of 39 reef coral genera to the 1998 bleaching event in the Indian Ocean found *Pocillopora* to be eighth-most susceptible of the 39 genera (McClanahan *et al.,* 2007). In a study carried out from 1997 to 2010 on the responses of a diverse reef coral assemblage in Japan to bleaching events in 1998 and 2001, *Pocillopora* species fared the worst of all genera, nearly dying out in 1998 and not recovering by 2010 (van Woesik, *et al.,* 2011). A meta-analysis of studies conducted between 1987 and 2012 at five locations in the Indo-Pacific (Moorea, GBR, Kenya, Hawaii, and Taiwan) found that the absolute and relative cover of many coral genera including *Pocillopora* declined in abundance, while some genera showed no change in abundance, and a few genera increased in abundance (Edmunds *et al.,* 2014).

(4) *Projected Effects of Warming-induced Mass Coral Bleaching.* Projections of ocean warming and subsequent mass coral bleaching suggest these events will increase in frequency, intensity, and magnitude across the Indo-Pacific, including the great majority of *P. meandrina*'s range. Hoeke *et al.* (2011) projected future changes to coral growth and mortality in the Hawaiian archipelago based the A1B scenario from the IPCC's Fourth Assessment Report (IPCC, 2007). This scenario assumes GHGs will peak in the mid-21st century then modestly decline as renewable energy becomes more common, and is most similar to RCP6.0 (IPCC, 2013). Despite the drop of GHGs in the late 21st century in the A1B scenario, this analysis projected precipitous declines in live coral cover (all reef corals combined, including *P. meandrina*) in the northwestern Hawaiian Islands between 2030 and 2050, and steady declines over the 21st century in the main Hawaiian Islands (Hoeke *et al.,* 2011). These results illustrate the concept of ''commitment'', *i.e.,* the world's oceans are currently committed to some future warming from the CO_2 build-up already in the atmosphere, even if anthropogenic emissions went to zero now (IPCC, 2013). As explained above, for the purpose of this finding, we will assume that RCP8.5 in IPCC's Fifth Assessment Report (IPCC, 2013) is the most likely pathway, but Hoeke *et al.* (2011) base their analysis on the more optimistic A1B scenario (similar to RCP6.0). Thus, we project that conditions in the Hawaiian Islands in the future will be worse than projected by Hoeke *et al.* (2011).

Projections of the responses of the world's corals and coral reefs ecosystems to ocean warming have been addressed recently by several papers that project coral responses to one or more of the IPCC's four pathways in the future. An analysis of the likely reef coral disease outbreaks resulting from ocean warming projected by RCP4.5 and RCP8.5 concluded that both pathways are likely to cause sharply increased, but spatially highly variable, levels of coral disease in the future, and that the outbreaks would be more widespread, frequent, and severe under RCP8.5 than RCP4.5 (Maynard *et al,* 2015). An analysis of the timing and extent of Annual Severe Bleaching (ASB) of the world's coral reefs under RCP4.5 vs RCP8.5 found that the global average timing of ASB would be only 11 years later under RCP4.5 than RCP8.5, and that >75 percent of all reefs still would experience ASB before 2070 under RCP4.5 (van Hooidonk *et al,* 2016). An analysis of the responses of coral reefs to increased warming and acidification under all four pathways found that only RCP2.6 would allow the current downward trend in coral reefs to stabilize, and that RCP4.5 would likely drive the elimination of most coral reefs by 2040–2050 (Hoegh-Guldberg *et al.,* 2017). Hughes *et al.,* (2017b) analyzed the responses of coral reefs to RCP2.6 and to the implementation of the 2015 Paris Agreement (which would result in a scenario roughly equivalent to RCP4.5)

and found that RCP2.6 would result in approximately the same amount of additional warming and bleaching by 2100 that has occurred over the last century, and that implementation of the Paris Agreement (*i.e.,* RCP4.5) would lead to severe consequences for coral reefs (Hughes *et al.,* 2017b), despite the fact that RCP6.0 and RCP8.5 would be even worse. Another analysis regarding responses of coral reefs if global warming is limited to 1.5°C, 2.0°C, or 3°C (roughly equivalent to RCP4.5, RCP6.0, and RCP8.5) found that estimated levels of thermal stress would be approximately seven, 11, and 23 times, respectively, the level of thermal stress that these reefs have already experienced since 1878, and approximately two, three, and six times the level of thermal stress experienced in 2016 (Lough *et al.,* 2018).

All five analyses considered the impacts of one or both of the IPCC's lower emissions pathways (RCP2.6 and RCP4.5), and each analysis reached the same conclusion: Even these lower emissions pathways are likely to have more severe impacts to reef corals in the future than have been observed in recent years (Hoegh-Guldberg *et al.,* 2017; Hughes *et al.,* 2017b; Lough *et al.,* 2018; Maynard *et al,* 2015; van Hooidonk *et al,* 2016), partially because the GHG emissions that have already occurred have irreversibly locked in a certain amount of warming due to ''commitment,'' as described above. Indo-Pacific reef corals would likely be even more severely impacted by warming-induced bleaching events resulting from ocean warming under the other two pathways in the future, especially RCP8.5, as shown by two analyses (Hoegh-Guldberg *et al.,* 2017b; van Hooidonk *et al,* 2016). Although *P. meandrina* has several life history characteristics that may buffer some of the effects of ocean warming (refer back to the Habitat, Range, and Life History section of this finding), based on the effects of warming-induced bleaching to date on *P. meandrina* and its relatively high susceptibility to warming, the information in the petition and other readily available information in our files suggests this species may be severely affected across its range in the future by ocean warming projected under RCP8.5.

Ocean Warming Summary. From the above analysis of ocean warming and its effects on *P. meandrina* and the coral reef community of which *P. meandrina* is a part, we find four key points to be relevant: (1) Substantial ocean warming, including in the tropical/subtropical Indo-Pacific, has already occurred and continues to occur; (2) ocean warming, including in the tropical/subtropical Indo-Pacific, is projected to continue at an accelerated rate in the future; (3) substantial warming-induced mass bleaching of Indo-Pacific reef coral communities, including *P. meandrina,* has already occurred and continues to occur; and (4) warming-induced mass bleaching of Indo-Pacific reef coral communities, including *P. meandrina,* is projected to steadily increase in frequency, intensity, and magnitude in the future. In short, ocean warming is expected to continue to affect *P. meandrina* throughout its range in the future.

Petition Finding

After reviewing the information presented in the petition and other readily available information in our files, we find that listing *P. meandrina* across its range may be warranted based on the threat of ocean warming alone. Therefore, in accordance with section 4(b)(3)(B) of the ESA and NMFS' implementing regulations (50 CFR 424.14), we will commence a status review of this species. During the status review, we will determine whether *P. meandrina* is in danger of extinction (endangered) or likely to become so (threatened) throughout all or a significant portion of its range. If listing is warranted, we will publish a proposed rule and solicit public comments before developing and publishing a final rule. If we determine that the species is in danger of extinction or likely to become so in the foreseeable future throughout all of its range, we will list the species as endangered or threatened, and it will be unnecessary to determine if Hawaii constitutes a significant portion of the species' range. If *P. meandrina* is not proposed for listing as endangered or threatened throughout all of its range, we will then determine if Hawaii constitutes a significant portion of the species' range. If so, we will determine the status of *P. meandrina* in Hawaii, and proceed accordingly (79 FR 37578; July 1, 2014).

Information Solicited

To ensure that the status review is based on the best available scientific and commercial data, we are soliciting information on whether *P. meandrina* is endangered or threatened. Specifically, we are soliciting information in the following areas:

(1) Historical and current distribution and abundance of *P. meandrina* throughout its range;

(2) Historical and current condition of *P. meandrina* and its habitat;

(3) Population density and trends of *P. meandrina;*

(4) The effects of climate change, including ocean warming and acidification, on the distribution and condition of *P. meandrina* and other organisms in coral reef ecosystems over the short- and long-term;

(5) The effects of other threats including dredging; coastal development; land-based sources of pollution, including coastal point source pollution, and agricultural and land use practices; disease, predation, the trophic effects of fishing, the aquarium trade, physical damage from boats and anchors, marine debris, aquatic invasive species on the distribution and abundance of *P. meandrina* over the short- and long-term; and the inadequacy of regulatory mechanisms; and

(6) Management programs for conservation of *P. meandrina,* including mitigation measures related to any of the threats listed under (5) above.

We request that all information be accompanied by (1) supporting documentation such as maps, bibliographic references, or reprints of pertinent publications; and (2) the submitter's name, address, and any association, institution, or business that the person represents.

References Cited

A complete list of references upon request from Lance Smith, NOAA IRC, NMFS/PIRO/PRD, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 17, 2018.

Samuel D. Rauch III,

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

[FR Doc. 2018–20512 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180212159–8159–01]

RIN 0648–BH75

Atlantic Highly Migratory Species; Shortfin Mako Shark Management Measures; Proposed Amendment 11; Comment Period Extension

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; extension of comment period.

SUMMARY: NMFS previously published, on July 27, 2018, a proposed rule to amend the 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) based on the results of the 2017 stock assessment and a subsequent binding recommendation by the International Commission for the Conservation of Atlantic Tunas (ICCAT) for North Atlantic shortfin mako sharks. The comment period on the proposed rule ends on October 1, 2018. In this extension of comment period, NMFS is extending the comment period to October 8, 2018, to provide an opportunity for the South Atlantic Fishery Management Council (Council) to be briefed, and to provide additional opportunities for the Council and other interested parties to comment on the proposed rule.

DATES: The deadline for receipt of comments on the proposed rule published on July 27, 2018 (83 FR 35637) is extended from October 1, 2018 to October 8, 2018.

ADDRESSES: You may submit comments on the referenced proposed rule published on July 27, 2018 (83 FR 35637), identified by NOAA–NMFS–2018–0011, by any one of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0011,* click the ''Comment Now'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Guý DuBeck, NMFS/SF1, 1315 East-West Highway, National Marine Fisheries Service, SSMC3, Silver Spring, MD 20910.

Instructions: Please include the identifier NOAA–NMFS–2018–0011 when submitting comments. Comments sent by any other method, to any other address or individual, or received after the close of the comment period, may not be considered by NMFS. All comments received are a part of the public record and generally will be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Guý DuBeck or Karyl Brewster-Geisz at (301) 427–8503.

SUPPLEMENTARY INFORMATION: The North Atlantic shortfin mako stock is managed primarily under the authority of the Magnuson-Stevens Act and also under the Atlantic Tunas Convention Act (ATCA). The 2006 Consolidated HMS FMP and its amendments are implemented by regulations at 50 CFR part 635.

On July 27, 2018 (83 FR 35637), NMFS published a proposed rule that announced NMFS' intent to amend the 2006 Consolidated Atlantic HMS FMP based on the results of the 2017 stock assessment and a subsequent binding recommendation by the International Commission for the Conservation of Atlantic Tunas (ICCAT) for North Atlantic shortfin mako sharks. The North Atlantic shortfin mako shark stock is overfished and is experiencing overfishing. Consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Atlantic Tunas Convention Act (ATCA), NMFS is proposing management measures that would reduce fishing mortality on shortfin mako sharks and establish a foundation for rebuilding the shortfin mako shark population consistent with legal requirements. In the proposed rule, the end of the comment period was announced as October 1, 2018. However, due to Hurricane Florence, the South Atlantic Fishery Management Council postponed its previously scheduled meeting by several weeks. Without an extension of the comment period, the Council would be unable to receive the same briefing provided to other Councils prior to providing comments on Amendment 11. As such, NMFS is extending the comment period to provide an opportunity to be briefed and an additional opportunity for the South Atlantic Fishery Management Council and other interested parties to comment on the proposed rule. Therefore, the comment period for the proposed rule is extended to October 8, 2018.

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

Dated: September 17, 2018.

Samuel D. Rauch III,

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

[FR Doc. 2018–20457 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 83, No. 183
Thursday, September 20, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meeting Notice of the National Agricultural Research, Extension, Education, and Economics Advisory Board

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, Section 1408 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3123), and the Agricultural Act of 2014, the United States Department of Agriculture (USDA) announces a virtual meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board.

DATES: The National Agricultural Research Extension, Education, and Economics Advisory Board will meet virtually by telephone conference on September 28, 2018, from 11:30 a.m.–1:00 p.m. Eastern Daylight Time (EDT). The public may file written comments before or up to October 12, 2018.

ADDRESSES: The meeting will take place virtually via teleconference.

Web Preregistration: Participants wishing to participate may preregister by calling 202–720–6012 or email at *nareee@ars.usda.gov.* Upon registration you will receive a call-in number and access code.

Written comments may be sent to: The National Agricultural Research, Extension, Education, and Economics Advisory Board Office, Room 332A, Whitten Building, United States Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–0321.

FOR FURTHER INFORMATION CONTACT: Michele Esch, Executive Director/Designated Federal Official, or Shirley Morgan-Jordan, Program Support Coordinator, National Agricultural Research, Extension, Education, and Economics Advisory Board; telephone: (202) 720–3684; fax: (202)720–6199; or email: *nareee@ars.usda.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the meeting: To provide advice and recommendations on the top priorities and policies for food and agricultural research, education, extension, and economics. The focus of this meeting will be on the deliberation of the following report and recommendations: The relevance and adequacy of the climate and energy needs programs of the USDA Research, Education, and Extension mission area; a report from the Science Advisory Council (a subcommittee of the NAREEE Advisory Board) on gene editing; and a report from the National Genetic Resources Advisory Council (a subcommittee of the NAREEE Advisory Board) on aquatic and animal genetic resources. A detailed agenda may be received from the contact person identified in this notice or at *https://nareeeab.ree.usda.gov/meetings/general-meetings.*

Tentative Agenda: On Tuesday, September 28, 2018, the meeting will be held from 11:00 a.m. EDT until 1:30 p.m. EDT.

Public Participation: This meeting is open to the public via telephone and any interested individuals wishing to attend. Opportunity for public comment will be offered. To attend the meeting via telephone and/or make oral statements regarding any items on the agenda, you must contact Michele Esch or Shirley Morgan-Jordan at 202–720–3684; email: *nareee@ars.usda.gov* at least 5 business days prior to the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. The Chair will conduct the meeting to facilitate the orderly conduct of business. Written comments by attendees or other interested stakeholders will be welcomed for the public record before and up to two weeks following the Board meeting (or by close of business Friday, October 12, 2018). All written statements must be sent to Michele Esch, Designated Federal Officer and Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, U.S. Department of Agriculture, Room 332A, Jamie L. Whitten Building, Mail Stop 0321, 1400 Independence Avenue SW, Washington, DC 20250–0321; or email: *nareee@ars.usda.gov.* All statements will become a part of the official record of the National Agricultural Research, Extension, Education, and Economics Advisory Board and will be kept on file for public review in the Research, Education, and Economics Advisory Board Office.

Done on at Washington, DC, this day of September 11, 2018.

Chavonda Jacobs-Young,

Acting, Deputy Under Secretary, Research, Education, and Economics Acting Chief Scientist.

[FR Doc. 2018–20452 Filed 9–19–18; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0058]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Fresh Peppers From Peru Into the Continental United States and the Territories

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of fresh peppers from Peru into the continental United States and the Territories.

DATES: We will consider all comments that we receive on or before November 19, 2018.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0058.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0058, Regulatory Analysis

and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0058* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the importation of fresh peppers from Peru into the continental United States and the Territories, contact Ms. Claudia Ferguson, Senior Regulatory Policy Coordinator, PPQ, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737; (301) 851–2532. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Fresh Peppers From Peru Into the Continental United States and the Territories.

OMB Control Number: 0579–0434.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–83).

The regulations in § 319.56–73 allow the importation of fresh peppers into the continental United States and the Territories from Peru. As a condition of entry, the peppers have to be produced in accordance with a systems approach that includes requirements for operational workplans, quality control programs, fruit fly trapping, pre-harvest production site inspections, production site and packinghouse registration, emergency action notifications, notices of arrival for imports, and packinghouse procedures designed to exclude quarantine pests. The peppers are also required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the national plant protection organization (NPPO) of Peru with an additional declaration stating that the consignment was produced in accordance with the systems approach outlined in the regulations. These actions allow for the importation of fresh peppers from Peru while continuing to provide protection against the introduction of plant pests into the United States and the Territories.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1 hour per response.

Respondents: Exporters, importers, and the NPPO of Peru.

Estimated annual number of respondents: 15.

Estimated annual number of responses per respondent: 16.

Estimated annual number of responses: 249.

Estimated total annual burden on respondents: 294 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 14th day of September 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2018–20449 Filed 9–19–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S Codex Program is sponsoring a public meeting on Tuesday, November 6, 2018. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 40th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) of the Codex Alimentarius Commission in Berlin, Germany November 26–30, 2018. The U.S. Manager for Codex Alimentarius and the Under Secretary, Office of Trade and Foreign Agricultural Affairs, recognize the importance of providing interested parties the opportunity to obtain background information on the 40th Session of the CCNFSDU and to address items on the agenda.

DATES: The public meeting is scheduled for Tuesday, November 6, 2018 from 1:00 p.m. to 3:00 p.m.

ADDRESSES: The public meeting will take place at the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition, Wiley Building, Room 1A002, 55 Campus Drive, College Park, MD 20740.

Documents related to the 40th Session of the CCNFSDU will be accessible via the internet at the following address: *http://www.codexalimentarius.org/meetings-reports/en.*

Dr. Douglas Balentine, U.S. Delegate to the 40th Session of the CCNFSDU, invites U.S. interested parties to submit their comments electronically to the following email address: *douglas.balentine@fda.hhs.gov.*

Call-In-Number: If you wish to participate in the public meeting for the 40th Session of the CCNFSDU by conference call, please use the call-in-number listed below:

Call-In-Number: 1–877–465–7975—U.S. Toll Free.

The participant code will be posted on the web page below: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/public-meetings.*

FOR FURTHER INFORMATION CONTACT:

About the 40th Session Of the CCNFSDU: Doug Balentine, Director, Office of Nutrition and Food Labelling, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5001 Campus Drive (HFS–830), College Park, MD 20740. Phone: +1 240 402 2373. Fax: +1 (301) 436–2636. Email: *Douglas.Balentine@fda.hhs.gov.*

About the Public Meeting: Doreen Chen-Moulec, U.S. Codex Office, 1400 Independence Avenue SW, Room 4861, South Agriculture Building, Washington, DC 20250, Phone: (202) 720–4063, Fax: (202) 720–3157, Email: *Doreen.Chenmoulec@osec.usda.gov.*

SUPPLEMENTARY INFORMATION:

Registration

Attendees may register to attend the public meeting by emailing *doreen.chenmoulec@osec.usda.gov* by October 24, 2018.

Early registration is encouraged because it will expedite entry into the building. The meeting will take place in a Federal building. Attendees should bring photo identification and plan for adequate time to pass through the security screening systems. Attendees who are not able to attend the meeting in person, but who wish to participate, may do so by phone, as discussed above.

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The CCNFSDU is responsible for:

(a) Studying nutrition issues referred to it by the Codex Alimentarius Commission;

(b) Drafting general provisions, as appropriate, on nutritional aspects of all foods and developing standards, guidelines, and related texts for foods for special dietary uses, in cooperation with other committees where necessary; and

(c) Considering, amending if necessary, and endorsing provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines, and related texts.

The CCNFSDU is hosted by Germany. The U.S. attends CCNFSDU as a member country of Codex.

Issues To Be Discussed at the Public Meeting

The following items on the Agenda for the 40th Session of the CCNFSDU will be discussed during the public meeting:

- Matters referred by the Codex Alimentarius Commission and its subsidiary bodies
- Matters of Interest Arising from FAO and WHO:
  - Review of the Standard for Follow-up Formula (CXS 156–1987)1
    - Comments in reply to CL 2018/62–NFSDU
  - Review of the Standard for Follow-up Formula (CXS 156–1987)2
    - Comments in reply to CL 2018/63–NFSDU
  - Proposed Draft Guideline for Ready-to-use Therapeutic Foods
    - Comments at in reply to CL 2018/64–NFSDU
  - Proposed Draft Definition for Biofortification
    - Comments in reply to CL 2018/65–NFSDU
  - Proposed Draft NRV–NCD for EPA and DHA long chain omega-3 fatty acids
    - Comments in reply to CL 2018/66–NFSDU
  - Proposed draft Claim for ''free'' of Trans Fatty Acids
    - Comments in reply to CL 2017/89/OCS–NFSDU
  - Discussion paper of NRV–R for older infants and young children
  - Discussion paper on mechanism/framework for considering the technological justification of food additives
  - Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements
  - Discussion paper on general guidelines to establish nutritional profiles
- Other Business and Future Work.

Each issue listed will be fully described in documents distributed, or to be distributed by the Secretariat before the Committee meeting. Members of the public may access or request copies of these documents (see **ADDRESSES**).

Public Meeting

At the Tuesday, November 6, 2018 public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Douglas Balentine, U.S. Delegate for the 40th Session of the CCNFSDU (see **ADDRESSES**). Written comments should state that they relate to activities of the 40th Session of the CCNFSDU.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.* The U.S. Codex Office also offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email. Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690–7442, *Email: program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on September 14th, 2018.

Mary Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2018–20443 Filed 9–19–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Codex Committee on Food Hygiene (CCFH)

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S Codex Office is sponsoring a public meeting on October 9, 2018. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 50th session of the Codex Committee on Food Hygiene (CCFH) of the Codex Alimentarius Commission in Panama City, Panama on November 12—16, 2018. The U.S. Manager for Codex Alimentarius and the Under Secretary, Office of Trade and Foreign Agricultural Affairs, recognize the importance of providing interested parties the opportunity to obtain background information on the 50th Session of the CCFH and to address items on the agenda.

DATES: The public meeting is scheduled for Tuesday, October 9, 2018 from 1:00 p.m. to 4 p.m.

ADDRESSES: The public meeting will take place at the United States Department of Agriculture (USDA), Jamie L. Whitten Building, 1400 Independence Avenue SW, Room 107–A, Washington, DC 20250. Documents related to the 50th Session of the CCFH will be accessible via the internet at the following address: *http://www.codexalimentarius.org/meetings-reports/en.*

Jenny Scott, U.S. Delegate to the 50th Session of the CCFH, invites U.S. interested parties to submit their comments electronically to the following email address: *Jenny.Scott@fda.hhs.gov.*

Call-In-Number: If you wish to participate in the public meeting for the 50th Session of the CCFH by conference call, please use the call-in-number listed below:

Call-In-Number: 1–888–844–9904.

The participant code will be posted on the web page below: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/public-meetings.*

FOR FURTHER INFORMATION CONTACT:

About the 50th Session Of The CCFH: Jenny Scott, Senior Advisor, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5001 Campus Drive HFS–300, Room 3B–014. College Park, MD 20740–3835 Phone: +1 (240) 402–2166. Fax: +1 (301) 436–2632. Email: *Jenny.Scott@fda.hhs.gov.*

About the Public Meeting: Barbara McNiff, U.S. Codex Office, 1400 Independence Avenue SW, Room 4861, South Agriculture Building, Washington, DC 20250 Phone: (202) 690–4719, Fax: (202) 720–3157, Email: *Barbara.McNiff@osec.usda.gov.*

SUPPLEMENTARY INFORMATION:

Registration

Attendees may register to attend the public meeting by emailing *Barbara.McNiff@osec.useda.gov* by October 3, 2018. Early registration is encouraged because it will expedite entry into the building. The meeting will take place in a Federal building. Attendees should bring photo identification and plan for adequate time to pass through the security screening systems. Attendees who are not able to attend the meeting in person, but who wish to participate, may do so by phone, as discussed above.

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The CCFH is responsible for:

- Developing basic provisions on food hygiene, applicable to all food or to specific food types;
- Considering and amending or endorsing provisions on food hygiene contained in Codex commodity standards and codes of practice developed by Codex commodity committees;
- Considering specific food hygiene problems assigned to it by the Commission;
- Suggesting and prioritizing areas where there is a need for microbiological risk assessment at the international level and developing questions to be addressed by the risk assessors; and
- Considering microbiological risk management matters in relation to food hygiene and in relation to the FAO/WHO risk assessments.

The CCFH is hosted by the United States. The 50th Session will be co-hosted by Panama and will convene in Panama City.

Issues To Be Discussed at the Public Meeting

The following items on the Agenda for the 50th Session of the CCFH will be discussed during the public meeting:

- Matters referred by the Codex Alimentarius Commission and its subsidiary bodies to the Food Hygiene
- Matters arising from the Work of FAO and WHO, including the Joint Expert Meeting on Microbiological Risk Assessment (JEMRA)
- Information from the World Organization for Animal Health (OIE)
- Proposed draft revision of the General Principles of Food Hygiene (CXC 1–1969) and its HACCP Annex
  - Comments in reply to CL 2018/69–FH
  - Revision to the Code of Practice for Fish and Fishery Products (CXC 52–2003): Placement for the guidance on histamine control; amendments to other sections, and revisions to the section on sampling, examination and analyses related to histamine food safety
  - Comments in reply to CL 2018/70–FH
  - Proposed draft code of practice on food allergen management for food business operators
  - Comments in reply to CL 2018/71–FH
  - Proposed draft guidance for the management of (micro) biological foodborne crises/outbreaks
  - Comments in reply to CL 2018/72–FH
- Discussion paper on future on work on Shiga toxin-producing Escherichia coli (STEC)
- Other business and Future Work
  - Proposals in reply to CL 2018/35–FH)

Each issue listed will be fully described in documents distributed, or to be distributed by the Secretariat before the Committee meeting. Members of the public may access or request copies of these documents (see **ADDRESSES**).

Public Meeting

At the October 9 public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the

meeting or sent to Jenny Scott, U.S. Delegate for the 50th Session of the CCFH (see **ADDRESSES**). Written comments should state that they relate to activities of the 50th Session of the CCFH.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.* The U.S. Codex Office also offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email.

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690–7442, Email: *program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on September 15th, 2018.

Mary Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2018–20442 Filed 9–19–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Colorado Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of bi-monthly planning meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Colorado Advisory Committee to the Commission will convene by conference call and video conference at 2:00 p.m. (EDT) on Friday, October 5, 2018. The purpose of the meeting is to plan for project planning.

DATES: Friday, October 5, 2018, at 2:00 p.m. (EDT).

Public Call-In Information: Conference call number: 1–888–395–3237 and conference call ID: 1659256.

Video Conference Information: Joining the meeting using audio and visual is a two-step process: For audio, dial: 1–888–395–3237; ID: 1659256. For video: Go to this link to register and join the meeting: *https://cc.readytalk.com/registration/#/?meeting=gexk5a8wrwg9&campaign=1kmq4ekr1j4l.* Note: although video conference is available, it is not required in order to listen to the conference call via audio.

If you have difficulty with the video link, try a browser other than Explorer or contact ReadyTalk Technical Support at: 1–800–843–9166. Note: Upon receipt of your registration confirmation email, you will receive a link to test your computer before the meeting, it would be advisable to do so.

FOR FURTHER INFORMATION CONTACT: Evelyn Bohor, *ebohor@usccr.gov* or by phone at 303–866–1040.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–888–395–3237 and conference call ID: 1659256; video conference link: *https://cc.readytalk.com/registration/#/?meeting=gexk5a8wrwg9&campaign=1kmq4ekr1j4l.*

Please be advised that, before being placed into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number provided.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call number: 1–888–395–3237 and conference call 1659256.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1040, or emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://www.facadatabase.gov/committee/meetings.aspx?cid=238;* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda

I. Roll Call
II. Project Planning
III. Other Business
IV. Adjournment

Dated: September 17, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–20498 Filed 9–19–18; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG484

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Ad Hoc Sablefish Management and Trawl Allocation Attainment Committee (SaMTAAC) will hold a meeting.

DATES: The meeting will be held Wednesday, October 10, 2018 and Thursday, October 11, 2018, starting at 8 a.m. and will end when business for the day has been completed.

ADDRESSES: The meeting will be held at the Hyatt Place Portland Airport, Meeting Place #3, 9750 NE Cascade Station, Portland, OR 97220; telephone: (503) 288–2808.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Dr. Jim Seger, Pacific Council; telephone: (503) 820–2416.

SUPPLEMENTARY INFORMATION: At this meeting, the SaMTAAC will continue to develop alternatives that address obstacles to achieving the goals and objectives of the groundfish trawl catch share plan related to under attainment of non-sablefish shore based trawl allocations and unharvested sablefish quota pounds south of 36° N. latitude. The committee's initial work on alternatives will be presented at the November 2018 Council meeting to solicit further Council guidance.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2411) at least 10 days prior to the meeting date.

Dated: September 17, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–20466 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG487

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scientific & Statistical Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, October 10, 2018 beginning at 9 a.m.

ADDRESSES:

Meeting address: The meeting will be held at the Hilton Garden Inn, Boston Logan, 100 Boardman Street, Boston, MA 02128; phone: (617) 567–6789.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scientific and Statistical Committee will review the results of the recent benchmark stock assessment (SAW/SARC 65) and information provided by the Council's Scallop Plan Development Team (PDT). The Committee will recommend the overfishing levels (OFLs) and acceptable biological catches (ABCs) for Atlantic sea scallops for fishing years 2019–20 (default). They will also review information provided by the Council's Herring PDT, the results from recent Atlantic herring benchmark stock assessment and using the acceptable biological catch (ABC) control rule selected by the Council, recommend the overfishing level (OFL) and the ABCs for Atlantic herring for 2019–21. Other business will be discussed as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: September 17, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–20467 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG486

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting; via webinar.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a meeting of its Mackerel Advisory Panel via webinar.

DATES: The webinar will convene on Tuesday, October 9, 2018, 1 p.m. to 3 p.m., EDT.

ADDRESSES:

Meeting address: The meeting will be held via webinar; visit the Gulf Council website for registration and log in information.

Council address: Gulf of Mexico Fishery Management Council, 4701 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, Fishery Biologist, Gulf of Mexico Fishery Management Council; *ryan.rindone@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Tuesday, October 9, 2018; 1 p.m.–3 p.m.;

I. Introductions and Adoption of Agenda (Item A1)
II. Approval of November 29, 2016 Mackerel AP report minutes (Item A2)
III. Review of CMP Framework Amendment 7—Modifications to Gulf Cobia Size and Possession Limits (Item A3)
IV. CMP FA7 Decision Document (Item A4)
V. AP Recommendations
VI. Other Business
—Meeting Adjourns

The meeting will held via webinar. You may register for the webinar by visiting *www.gulfcouncil.org* and clicking on the Mackerel Advisory Panel meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Advisory Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Advisory Panel will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Dated: September 17, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–20465 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG297

Marine Mammals; File No. 21425

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Point Blue Conservation Science, has applied in due form for a permit to conduct research on pinnipeds in California.

DATES: Written, telefaxed, or email comments must be received on or before October 22, 2018.

ADDRESSES: The application 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. 21425 from the list of available applications.

These documents are 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. 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: Sara Young or Shasta McClenahan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The proposed permit would authorize research to study and monitor population trends, health, and ecology of pinnipeds in California. Each year, up to 2,210 Northern elephant seals (*Mirounga angustirostris*) and 500 northern fur seal (*Callorhinus ursinus*) will be tagged, marked, and handled annually. A maximum estimated 4,000 harbor seals (*Phoca vitulina*), 2,500 Northern elephant seals, 2,200 California sea lions (*Zalophus californianus*), 320 Steller sea lions (*Eumetopias jubatus*) and 1,250 northern fur seals will be incidentally disturbed annually during pinniped research operations including ground surveys, scat collection, unmanned aircraft system operations, and adult/pup tagging. The permit would be valid for five years from date of issuance.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–20477 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review 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.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman (Permit No. 21233), Erin Markin (Permit No. 20561), and Carrie Hubard (Permit No. 22292); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the research, go to *www.federalregister.gov* and search on the permit number provided in the table below.

Permit No.	RIN	Applicant	Previous **Federal Register** Notice	Permit or Amendment Issuance Date
20561	0648–XG282	Virginia Aquarium and Marine Science Center (Responsible Party: W. Mark Swingle), 717 General Booth Boulevard, Virginia Beach, VA 23451.	83 FR 28413; June 19, 2018.	8/24/18
21233	0648–XG104	NMFS Southeast Fisheries Science Center (Responsible Party: Theophilus Brainerd, Ph.D.), 75 Virginia Beach Drive, Miami, FL 33149.	83 FR 13477; March 29, 2018.	8/7/18
22292	0648–XG319	Icon Films, (Responsible Party: Laura Marshall), 3rd Floor College House, 32–36 College Green, Bristol, BS1 5SP, United Kingdom.	83 FR 30916; July 2, 2018.	8/3/2018

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 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), as applicable.

Dated: September 17, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–20479 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Meeting of the Columbia Basin Partnership Task Force of the Marine Fisheries Advisory Committee

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

ACTION: Notice of open public meeting.

SUMMARY: This notice sets forth the proposed schedule and agenda of a forthcoming meeting of the Marine Fisheries Advisory Committee's (MAFAC's) Columbia Basin Partnership Task Force (CBP Task Force). The CBP Task Force will discuss the issues outlined in the **SUPPLEMENTARY INFORMATION** below.

DATES: The meeting will be held October 2, 2018, from 8 a.m. to 5 p.m. and on October 3, 2018, from 8 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Port of Portland, 7200 NE Airport Way, Portland, OR 97218; 503–415–6000.

FOR FURTHER INFORMATION CONTACT: Katherine Cheney; NFMS West Coast Region; 503–231–6730; email: *Katherine.Cheney@noaa.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given of a meeting of MAFAC's CBP Task Force. The MAFAC was established by the Secretary of Commerce (Secretary) and, since 1971, advises the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. The MAFAC charter and meeting information are located online at *https://www.fisheries.noaa.gov/topic/partners#marine-fisheries-advisory-committee-.* The CBP Task Force reports to MAFAC and is being convened to develop recommendations for long-term goals to meet Columbia Basin salmon recovery, conservation needs, and harvest opportunities, in the context of habitat capacity and other factors that affect salmon mortality. More information is available at the CBP Task Force web page: *http://www.westcoast.fisheries.noaa.gov/columbia_river/index.html.*

Matters To Be Considered

The meeting time and agenda are subject to change. Meeting topics include continuing to seek agreement on qualitative and quantitative goals for Columbia Basin salmon and steelhead, discussing approaches to integrate the information towards developing basin-wide goals, and working on the draft recommendations report. The meeting is open to the public as observers, and public input will be accepted on October 3, 2018, from 1:30 to 2 p.m.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Katherine Cheney, 503–231–6730, by September 25, 2018.

Dated: September 17, 2018.

Jennifer L. Lukens,

Federal Program Officer, Marine Fisheries Advisory Committee, National Marine Fisheries Service.

[FR Doc. 2018–20511 Filed 9–19–18; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Technology Advisory Committee; Meeting

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of meeting.

SUMMARY: The Commodity Futures Trading Commission (CFTC) announces that on October 5, 2018, from 10:00 a.m. to 3:30 p.m., the Technology Advisory Committee (TAC) will hold a public meeting in the Conference Center at the CFTC's Washington, DC, headquarters. At this meeting, the TAC will hear presentations and actionable recommendations from select TAC subcommittees (potentially including Automated and Modern Trading Markets; Distributed Ledger Technology and Market Infrastructure; Virtual Currencies; and Cyber Security subcommittees); and discuss how RegTech is opening up the possibility of machine readable and executable regulatory rulebooks (*i.e.,* Robo Rulebooks), as well as the potential role of regulators.

DATES: The meeting will be held on October 5, 2018, from 10:00 a.m. to 3:30 p.m. Members of the public who wish to submit written statements in connection with the meeting should submit them by October 12, 2018.

ADDRESSES: The meeting will take place in the Conference Center at the CFTC's headquarters, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. You may submit public comments, identified by ''Technology Advisory Committee,'' by any of the following methods:

- *CFTC website: https://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail, above.

Any statements submitted in connection with the committee meeting will be made available to the public, including publication on the CFTC website, *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel Gorfine, TAC Designated Federal Officer, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581; (202) 418–5625.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public with seating on a first-come, first-served basis. Members of the public may also listen to the meeting by telephone by calling a domestic toll-free telephone or international toll or toll-free number to connect to a live, listen-only audio feed. Call-in participants should be prepared to provide their first name, last name, and affiliation.

Domestic Toll Free: 1–877–951–7311

International Toll and Toll Free: Will be posted on the CFTC's website, *http://www.cftc.gov,* on the page for the meeting, under Related Links.

Pass Code/Pin Code: 5965976

The meeting agenda may change to accommodate other TAC priorities. For agenda updates, please visit the TAC committee site at: *http://www.cftc.gov/About/CFTCCommittees/TechnologyAdvisory/tac_meetings.*

After the meeting, a transcript of the meeting will be published through a link on the CFTC's website, *http://www.cftc.gov.* All written submissions provided to the CFTC in any form will also be published on the CFTC's website. Persons requiring special accommodations to attend the meeting because of a disability should notify the contact person above.

Authority: 5 U.S.C. app. 2, sec. 10(a)(2).

Dated: September 17, 2018.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2018–20508 Filed 9–19–18; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Wednesday, September 26, 2018.

PLACE: Three Lafayette Centre, 1155 21st Street NW, Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Examinations and enforcement matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

Natise L. Allen,

Secretariat Program Assistant.

[FR Doc. 2018–20540 Filed 9–18–18; 11:15 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before October 22, 2018.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA), in OMB, within 30 days of this notice's publication by either of the following methods. Please identify the comments by ''OMB Control No. 3038–97.

- *By email addressed to: OIRAsubmissions@omb.eop.gov* or
- *By mail addressed to:* the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW, Washington, DC 20503.

A copy of all comments submitted to OIRA should be sent to the Commodity Futures Trading Commission (the ''Commission'') by any of the following methods. The copies should refer to ''OMB Control No. 3038–0097.''

- *By mail addressed to:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581;
- By Hand Delivery/Courier to the same address; or
- Through the Commission's website at *https://comments.cftc.gov.* Please follow the instructions for submitting comments through the website.

A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting *https://RegInfo.gov.*

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.* You should submit only

information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures set forth in section 145.9 of the Commission's regulations.[1] The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Megan Wallace, Senior Special Counsel, Division of Clearing and Risk, Commodity Futures Trading Commission, (202) 418–5150; email: *mwallace@cftc.gov.*

SUPPLEMENTARY INFORMATION:

Title: Part 39, Process for Review of Swaps for Mandatory Clearing (OMB Control No. 3038–0097). This is a request for extension and revision [2] of a currently approved information collection.

Abstract: The Commodity Exchange Act and Commission regulations require a derivatives clearing organization (''DCO'') that wishes to accept a swap for clearing to be eligible to clear the swap and to submit the swap to the Commission for a determination as to whether the swap is required to be cleared. Commission Regulation 39.5 sets forth the process for these submissions. The Commission uses the information in this collection to determine whether a DCO that wishes to accept a swap for clearing is eligible to clear the swap and whether the swap should be required to be cleared.

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. On July 6, 2018, the Commission published in the **Federal Register** notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 83 FR 31530 (''60-Day Notice''). The Commission did not receive any relevant comments on the 60-Day Notice.

Burden Statement: The respondent burden for this collection is estimated to be as follows:

Respondents/Affected Entities: Derivatives clearing organizations.

Estimated Number of Respondents: 16.

Estimated Average Burden Hours per Respondent: 40.

Estimated Total Annual Burden Hours: 640 hours.

Frequency of Collection: On occasion.[3]

Authority: 44 U.S.C. 3501 *et seq.*

Dated: September 17, 2018.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2018–20509 Filed 9–19–18; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

[2] The total number of respondents has been increased from 14 in 2015 to 16 in 2018, based on the current number of registered DCOs, thus increasing the total annual burden hours from the previous 560 hours (40 hrs/response × 14) to 640 hours (40 hrs./response × 16) currently.

[3] While the 60-Day Notice indicates ''daily, annual, and on occasion,'' the frequency of information collection is only ''on occasion'' based on current data.

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings

TIME AND DATE: Wednesday, September 26, 2018, 10:00 a.m.–12:00 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD.

STATUS: Commission Meeting—Open to the Public.

MATTER TO BE CONSIDERED: Briefing Matter: Fiscal Year 2019 Operating Plan.

A live webcast of the Meeting can be viewed at *https://www.cpsc.gov/live.*

CONTACT PERSON FOR MORE INFORMATION: Rockelle Hammond, Office of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–6833.

Dated: September 18, 2018.

Alberta E. Mills,

Secretary.

[FR Doc. 2018–20607 Filed 9–18–18; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2016–HQ–0038]

Proposed Collection; Comment Request

AGENCY: Department of the Army, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by November 19, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Product Manager for Force Protection Systems (PdM–FPS), 5900 Putnam Road, Building 365/Suite 1, (SFAE–IEW–TF),

ATTN: Mark Shuler, Fort Belvoir, VA 22060–5420, or call PdM–FPS at 703–704–2402.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Automated Installation Entry (AIE) System; OMB Control Number 0702–0125.

Needs and Uses: The information collection requirement is necessary to verify the identity of an individual and determine the fitness of an individual requesting and/or requiring access to installations, and issuance of local access credentials. The information collection methodology involves the employment of technological collection of data via an electronic physical access control system (PACS) which provides the capability to rapidly and electronically authenticate credentials and validate and individual's authorization to enter an installation.

Affected Public: Individuals or Households; Business or Other For-Profit.

Annual Burden Hours: 44,315 Hours.

Number of Respondents: 886,294.

Responses per Respondent: 1.

Annual Responses: 886,294.

Average Burden per Response: 3 minutes.

Frequency: On Occasion.

Dated: September 17, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–20486 Filed 9–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0034]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 22, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Exceptional Family Member Program (EFMP) Family Needs Assessment (FNA); DD X768; OMB Control Number 0704–XXXX.

Type of Request: New collection.

Number of Respondents: 20,000.

Responses per Respondent: 1.

Annual Responses: 20,000.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 10,000.

Needs and Uses: This information collection is necessary to address current differences in assessment processes and inconsistent transfer of cases across the Services. With this standardized form, installation-level EFMP Family Support Offices can provide a family support experience that is consistent across the Services and maintains continuity of services when military families with special needs have Permanent Change of Station (PCS) orders to a joint base or sister-Service location.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: September 17, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–20482 Filed 9–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0015]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: 30-day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 22, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Personnel Security System Access Request (PSSAR) Form; DD Form 2962–1, DD Form 2962–2; OMB Control Number 0704–0542.

Type of Request: Revision.

Number of Respondents: 22,225.

Responses per Respondent: 1.

Annual Responses: 22,225.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 3,704.

Needs and Uses: The information collection requirement is necessary because the Joint Personnel Adjudication System, Defense Information System for Security, Secure Web Fingerprint Transmission, and Defense Central Index of Investigations require personal data collection to facilitate the granting of access to the suite of DMDC systems to Security Managers for the purpose of the initiation, investigation and adjudication of information relevant to

DoD security clearances and employment suitability determinations for active duty military, civilian employees and contractors requiring the aforementioned clearances. As a suite of Personnel Security Systems, they are the authoritative source for clearance information resulting in accesses determinations to sensitive/classified information and facilities.

Affected Public: Business or other for-profit.

Frequency: As required.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: September 17, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–20485 Filed 9–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–27]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–27 with attached Policy Justification and Sensitivity of Technology.

Dated: September 17, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

JUL 3 1 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-27, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of the Netherlands for defense articles and services estimated to cost $169 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–27

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* The Government of the Netherlands

(ii) *Total Estimated Value:*

Major Defense Equipment *	$122 million
Other	$ 47 million
Total	$169 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

One hundred six (106) MK 54 Lightweight Torpedo Conversion Kits

Non-MDE:

Also included are torpedo containers, Recoverable Exercise Torpedoes (REXTORP) with containers; Fleet Exercise Section (FES) and fuel tanks; air launch accessories for rotary wing aircraft; torpedo launcher interface cabinets; ground handling equipment; torpedo spare parts; training; publications; support and test equipment; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistics and program support.

(iv) *Military Department:* Navy (NE–P–LHP)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* July 31, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

The Netherlands—MK 54 Lightweight Torpedoes

The Netherlands requests to buy one hundred six (106) MK 54 conversion kits. Also included are torpedo containers, Recoverable Exercise Torpedoes (REXTORP) with containers; Fleet Exercise Section (FES) and fuel tanks; air launch accessories for rotary wing aircraft; torpedo launcher interface cabinets; ground handling equipment; torpedo spare parts; training; publications; support and test equipment; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistics and program support. The estimated program value is $169 million.

This proposed sale will support the foreign policy and national security objectives of the United States by improving the security of a NATO Ally, which is an important force for political stability and economic progress in Europe.

The Royal Netherlands Navy intends to upgrade its current MK 46 torpedoes to the MK 54 with the purchase of these kits. The Netherlands will have no difficulty absorbing the MK 54 torpedoes.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Raytheon Integrated Defense System, Portsmouth, Rhode Island. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Netherlands; however, U.S. Government Engineering and Technical Services may be required on an interim basis for installations and integration.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–27

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex Item No. vii

(vii) *Sensitivity of Technology:*

1. The MK 54 Torpedo is a conventional torpedo that can be launched from surface ships, helicopters, and fixed wing aircraft. The MK 54 is an upgrade to the MK 46 Torpedo, which is currently in-service in Netherlands. The upgrade to the MK 54 entails replacement of the torpedo's sonar and guidance and control systems with modem technology. The new guidance and control system uses a mixture of commercial-off-the-shelf and custom-built electronics. The warhead, fuel tank and propulsion system from the MK 46 torpedo are re-used in the MK 54 configuration with minor modifications. There is no sensitive technology in the MK 54 or its support and test equipment. The assembled MK 54 torpedo and several of its individual components are classified CONFIDENTIAL. The MK 54 operational software is classified as SECRET. Netherlands will not be provided with the source code for the MK 54 operational software.

2. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the Government of the Netherlands can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to the Netherlands.

[FR Doc. 2018–20507 Filed 9–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2018–HQ–0015]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of the Navy, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of Civilian Human Resources announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by November 19, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the Assistant Secretary of the Navy, Office of Civilian Human Resources (ASN/OCHR), 614 Sicard Street, Building 201, Washington, DC 20374 or call OCHR at [202–685–6466].

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of the Navy (DON) Reasonable Accommodations (RA) Tracker; SECNAV Form 12306/1T Confirmation of Reasonable

Accommodation Request; OMB Control Number 0703–0063.

Needs and Uses: The information collection requirement is necessary to track, monitor, review, and process requests for reasonable accommodation applicants for employment. This information will be collected by DON EEO personnel involved in the Reasonable Accommodation process and input data into the Reasonable Accommodation Tracker (electronic information system) pursuant to Executive Order 13163. Official Reasonable Accommodation case files are secured with access granted on a strictly limited basis.

Affected Public: Individuals or Households.

Annual Burden Hours: 33.

Number of Respondents: 100.

Responses per Respondent: 1.

Annual Responses: 100.

Average Burden per Response: 20 minutes.

Frequency: On occasion.

The Department of the Navy Reasonable Accommodation Tracker will maintain employment information, contact information, and information related to the disabilities and reasonable accommodations/potential reasonable accommodations for employees, contractors, and applicants for employment who request reasonable accommodations. Reasonable accommodations applicants complete SECNAV 12306/1T Form-Confirmation of Reasonable Accommodation Request, information from the form will be input into the Reasonable Accommodation Tracker. Contact information of deciding officials and health care providers will also be maintained in the system. Data collected is required for DON EEO officials and employees to track, monitor, review, and process requests for reasonable accommodations. Individuals involved in the reasonable accommodation process would not be able to perform their official duties of processing or deciding on cases if the subject information is not collected and maintained by DON EEO personnel. Official Reasonable Accommodation case files are secured with access granted on a strictly limited basis. Case files will be retained for the duration of that individual's employment with the Department of the Navy. Case files maintained will be retained and disposed of in accordance with the provisions of the OPM Government wide Systems of Records, 65 CFR 27432.

Dated: September 17, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–20489 Filed 9–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2018–HQ–0014]

Privacy Act of 1974; System of Records; Correction

AGENCY: Department of the Navy, DoD.

ACTION: Notice of a modified system of records; correction.

SUMMARY: On September 5, 2018, the Department of Defense published a system of records notice that proposed to modify Family and Unaccompanied Housing Program, NM11101–1. Subsequent to the publication of the notice, DoD discovered that the system number had published incorrectly. This notice corrects that error.

DATES: This correction is applicable on September 20, 2018.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION:

Correction

On September 5, 2018 (83 FR 45112–45115), the Department of Defense published a system of records notice, FR Doc. 2018–19204, that proposed to modify Family and Unaccompanied Housing Program, NM11101–1. Subsequent to the publication of the notice, DoD discovered that the system name had published incorrectly. The system name incorrectly published as ''NM1110–01'' in the two places it appeared in the notice. The system name is corrected as follows:

1. On page 45112, in the first column, in the SUMMARY paragraph, ''NM1110–01'' is corrected to read ''NM11101–1.''

2. On page 45112, in the third column, in the SYSTEM NAME AND NUMBER paragraph, ''NM1110–01'' is corrected to read ''NM11101–1.''

Dated: September 17, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–20513 Filed 9–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0099]

Agency Information Collection Activities; Comment Request; Borrower Defenses Against Loan Repayment

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 November 19, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0099. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 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: Borrower Defenses Against Loan Repayment.

OMB Control Number: 1845–0132.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 150,000.

Total Estimated Number of Annual Burden Hours: 150,000.

Abstract: This is a request for an extension of the current information collection for Form 1845–0132. The U.S. Department of Education continues to require the collection of this information from borrowers who believe they have cause to invoke the borrower defense to loan repayment forgiveness of a student loan. There is no change to statutory or regulatory requirements. This collection continues to be necessary to ensure Heald, Everest and/or WyoTech College borrowers who wish to invoke the borrower defense against repayment of federal student loans can do so in a uniform and informed manner. It will also allow for the uniform and directed collection of minimum borrower defense information from other federal student loan borrowers that attended the school who believe they can provide evidence of such an application for loan forgiveness.

Dated: September 17, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–20456 Filed 9–19–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meetings

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: September 20, 2018 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda

Note: Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *http://ferc.capitolconnection.org/* using the eLibrary link, or may be examined in the Commission's Public Reference Room.

1047TH—MEETING

[Open Meeting September 20, 2018 10:00 p.m.]

Item No.	Docket No.	Company
	ADMINISTRATIVE	
A–1	AD18–2–000	Customer Matters, Reliability, Security and Market Operations.
A–2	AD18–1–000	Agency Administrative Matters.
A–3	AD18–17–000	Memorandum of Understanding Between the Department of Transportation and the Federal Energy Regulatory Commission Regarding Liquefied Natural Gas Transportation Facilities.
	ELECTRIC	
E–1	EL18–152–000	Louisiana Public Service Commission v. System Energy Resources, Inc. and Entergy Services, Inc.
E–2	EL16–120–002	New England Power Generators Association, Inc. v. ISO New England Inc.
	ER17–2153–002	ISO New England. Inc.
	ER18–1153–000	ISO New England, Inc.
E–3	ER10–1791–004	Midwest Independent Transmission System Operator, Inc.
E–4	ER17–2073–001	PJM Interconnection, L.L.C.
E–5	ER17–2267–001	PJM Interconnection, L.L.C.
E–6	ER14–2154–006 ER15–277–005 (consolidated)	Midcontinent Independent System Operator, Inc.
E–7	EL17–44–000	Northern States Power Company, Minnesota.
E–8	EL18–145–000	Tilton Energy LLC v. PJM Interconnection, L.L.C.
E–9	ER14–1409–000	ISO New England Inc.
E–10	EL18–131–000	Nevada Hydro Company, Inc.
E–11	ER17–1750–002	Pacific Gas and Electric Company.
	GAS	
G–1	OMITTED.	
G–2	OMITTED.	
G–3	OR18–7–000	Epsilon Trading, LLC, Chevron Products Company, and Valero Marketing and Supply Company v. Colonial Pipeline Company.

1047TH—MEETING—Continued

[Open Meeting September 20, 2018 10:00 p.m.]

Item No.	Docket No.	Company
	OR18–12–000	BP Products North America, Inc., Trafigura Trading LLC, and TCPU, Inc. v. Colonial Pipeline Company.
	OR18–17–000	TransMontaigne Product Services LLC v. Colonial Pipeline Company.
	OR18–21–000 (consolidated)	CITGO Petroleum Corporation v. Colonial Pipeline Company.
HYDRO		
H–1	EL18–56–000	Utah Board of Water Resources.
	P–12966–005	
H–2	P–2611–087	Hydro-Kennebec LLC.
CERTIFICATES		
C–1	CP09–465–002	Northern Natural Gas Company.
C–2	CP17–219–000	Southern Star Central Gas Pipeline, Inc.

Issued: September 13, 2018.

Kimberly D. Bose,

Secretary.

A free webcast of this event is available through *http://ferc.capitolconnection.org/.* Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *http://ferc.capitolconnection.org/* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2018–20619 Filed 9–18–18; 4:15 pm]

BILLING CODE 6717–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, September 25, 2018 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC.

STATUS: This Meeting will be Closed to the Public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109. Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Laura E. Sinram,

Deputy Secretary of the Commission.

[FR Doc. 2018–20632 Filed 9–18–18; 4:15 pm]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Depression in Children: Systematic Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Depression in Children: Systematic Review,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before October 22, 2018.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Depression in Children: Systematic Review.* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a). The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Depression in Children: Systematic Review,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://effectivehealthcare.ahrq.gov/topic/childhood-depression/protocol*

This is to notify the public that the EPC Program would find the following

information on *Depression in Children: Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions (KQs)

1a. In adolescents and children, what are the benefits and harms of nonpharmacological interventions for depressive disorders (defined as MDD or PDD/DD)?

1b. How do these benefits and harms vary by subpopulation (*e.g.,* patient characteristics, parent/caregiver characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

2a. In adolescents and children, what are the benefits and harms of pharmacological interventions for depressive disorders (defined as MDD or PDD/DD)?

2b. How do the benefits and harms vary by subpopulation (*e.g.,* patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event?

3a. In adolescents and children, what are the benefits and harms of combination interventions for depressive disorders (defined as MDD or PDD/DD)?

3b. How do the benefits and harms vary by subpopulation (*e.g.,* patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

4a: In adolescents and children, what are the benefits and harms of collaborative care interventions for depressive disorders (defined as MDD or PDD/DD)?

4b: How do the benefits and harms vary by subpopulation (*e.g.,* patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

5a: In adolescents and children, what are the comparative benefits and harms of treatments (pharmacological, nonpharmacological, combined, collaborative care interventions) for depressive disorders (defined as MDD or PDD/DD)?

5b. How do these benefits and harms vary by subpopulation (*e.g.,* patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

TABLE 1—PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS) AND INCLUSION/EXCLUSION CRITERIA

PICOTS	Inclusion	Exclusion
Population	Children and adolescents (≤18 years old) with a depressive disorder (MDD or PDD/DD) as indicated by a diagnosis made from an established taxonomy (*e.g.,* DSM, ICD) via administration of a structured or semi-structured clinical interview (CIDI, DISC, SCID, PRIME–MD, Kinder-DIPS, K–SADS, DICA, CAS, SADS, DAWBA, SCAN), use of a cutpoint indicative of clinical MDD or PDD/DD as measured by a clinically validated depression scale (BDI, CDI, CESD, PHQ, MFQ, ChilD–S),* or via a clinician diagnosis. Subgroups of interest (KQs 1b, 2b, 3b, 4b, 5b) include those distinguished by patient characteristics (*e.g.,* developmental age—child or adolescent, gender, race/ethnicity), parent/caregiver characteristics, disorder characteristics (*e.g.,* type, severity), history of previous treatment, comorbid condition, and exposure to a traumatic life event.	All other children and adolescents (≤18 years old); all adults >18 years old.
Intervention	Nonpharmacological interventions: *Psychological/psychosocial:* Cognitive behavioral therapy, rational emotive behavior therapy, behavioral activation, other behavioral therapy, interpersonal therapy, directive counseling, Katathym-imaginative Psychotherapy, family therapy, parent education, self-help groups, problem-solving therapy, autonomic training, combined-modality therapy, psychological adaptation therapies.	All other interventions.

TABLE 1—PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS) AND INCLUSION/EXCLUSION CRITERIA—Continued

PICOTS	Inclusion	Exclusion
	Lifestyle: Exercise (physical activity), diet therapy, mindfulness (including mindfulness-based stress reduction), meditation (including mindfulness mediation), relaxation therapy, massage therapy, music therapy, art therapy, integrative restoration, visualization, tai-chi, yoga, spirituality, acupuncture. *Supplements:* St. John's Wort, SAMe, fish oil, melatonin, L-tryptophan, folic acid, 5–HTP, zinc, chromium, gingko biloba, vitamin E, omega-3 fatty acids, hypericum, inositol, selenium. *Other:* Electroconvulsive therapy, transcranial magnetic stimulation, light therapy (phototherapy), hypnotherapy (including self-hypnotherapy), neurofeedback, deep brain stimulation, biofeedback. Pharmacological interventions:. *Selective serotonin reuptake inhibitors (SSRIs):* Citalopram, escitalopram, fluvoxamine, paroxetine, sertraline, vilazodone. *Serotonin and norepinephrine reuptake inhibitors (SNRIs):* Duloxetine, venlafaxine. *Tricyclic antidepressants: Amitriptyline,* desipramine, imipramine, nortriptyline, doxepin, *clomipramine*. *Monoamine oxidase inhibitors: Rasagiline, selegiline, isocarboxazid, phenelzine, tranylcypromine*. *Atypical antidepressants:* Bupropion, mirtazapine, nefazodone, trazodone, vortioxetine. Combination interventions: Any combined treatment that includes two or more types of nonpharmacological, pharmacological, and/or collaborative care interventions, either started together or given as augments to initial treatment types. Collaborative care interventions: Collaborative care, integrated care, integrative care, stepped care, coordinated care, co-managed care, co-located care.	
Comparator	KQ 1: Treatment as usual, sham, attention control, wait list control KQ 2: Placebo, treatment as usual, attention control, wait list control. KQ 3: Treatment as usual, placebo, sham, attention control, wait list control. KQ 4: Treatment as usual, placebo, sham, attention control, wait list control. KQ 5: Any nonpharmacologic, pharmacologic, or collaborative care intervention alone or in combination.	All other comparators.
Outcomes****	Benefits: Remission. Response. Relapse. Depressive symptoms. Suicidality. Mortality. Functional impairment. Harms: Any AEs of intervention (*e.g.,* death, serious adverse events).	All other outcomes.
Time frame	Any publication dates At least 6 weeks of treatment.	Less than 6 weeks of treatment.
Settings	Outpatient care in countries with a very high Human Development Index**.	Inpatient care, studies conducted in countries without a very high Human Development Index.
Study design	For benefits: • Adolescents (sample age >12 and ≤18): randomized controlled trials (RCTs). • Children (sample age ≤12): RCTs or controlled clinical trials (CCTs). For harms: • RCTs, CCTs, and observational studies***. Reference lists of relevant systematic reviews published in 2013 or later will be used to ensure our search strategies captured all relevant studies.	All other designs and studies using included designs that do not meet the sample size criterion.
Language	Studies published in English	Studies published in languages other than English.

* In the absence of clear, clinically validated cutoffs of depression scales used to indicate a either MDD or PDD/DD, the research team will consult two recent systematic reviews [1 2] on the topic and discuss required thresholds with the Technical Expert Panel (TEP) for each scale.

** *http://hdr.undp.org/en/content/human-development-index-hdi*.

*** The research team will evaluate the yield for harms. When studies with sample sizes of 1,000 or more participants are available for a given intervention and comparator, the team plans to restrict the analysis to that group. If large samples are not available, the team plans to include studies with smaller sample sizes.

**** The research team anticipates grading all outcomes but if needed (based on the volume of evidence), they may seek input from the TEP on prioritizing outcomes for strength of evidence grading.

AE = adverse event; BDI = Beck Depression Inventory; CAS: The Child Assessment Schedule; CBT = cognitive behavioral therapy; CCT = controlled clinical trial; CIDI = Composite International Diagnostic Interview; CDI = Children's Depression Inventory; CES–D = Center for Epidemiological Studies Depression Scale; ChilD–S: Children's Depression Screener; DAWBA = The Development and Wellbeing Assessment; DD = dysthymic disorder; DICA = Diagnostic Interview for Children and Adolescents; DISC = Diagnostic Interview Schedule for Children; DSM = *Diagnostic and Statistical Manual;* IPT = interpersonal therapy; Kinder-DIPS = The Diagnostic Interview for Psychiatric Disorders in Children and Adolescents; K–SADS = The Schedule for Affective Disorders and Schizophrenia for School-Age Children; MDD = major depressive disorder; MFQ = Mood and Feelings Questionnaire; PDD = persistent depressive disorder; PHQ = Patient Health Questionnaire; PICOTS = populations, interventions, comparators, outcomes, timing, and setting; PRIME–MD = The Primary Care Evaluation of Mental Disorders; RCT = randomized controlled trial; SADS = The Schedule for Affective Disorders and Schizophrenia; SCAN = Schedules for Clinical Assessment in Neuropsychiatry; SCID = Structured Clinical Interview for DSM disorders.

References

1. Roseman M, Kloda LA, Saadat N, et al. Accuracy of Depression Screening Tools to Detect Major Depression in Children and Adolescents: A Systematic Review. Can J Psychiatry. 2016 Dec;61(12):746–57. doi: 10.1177/0706743716651833. PMID: 27310247.
2. Stockings E, Degenhardt L, Lee YY, et al. Symptom screening scales for detecting major depressive disorder in children and adolescents: a systematic review and meta-analysis of reliability, validity and diagnostic utility. J Affect Disord. 2015 Mar 15;174:447–63. doi: 10.1016/j.jad.2014.11.061. PMID: 25553406.

Francis D. Chesley, Jr.,

Deputy Director.

[FR Doc. 2018–20481 Filed 9–19–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Performance Review Board Members

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) located within the Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members who are reviewing performance for Fiscal Year 2018.

FOR FURTHER INFORMATION CONTACT: Sandra DeShields, Chief, Compensation and Performance Management Team, Executive and Scientific Resources Office, Human Resources Office, Centers for Disease Control and Prevention, 11 Corporate Square Blvd., Mailstop US11–2, Atlanta, Georgia 30341, Telephone (770) 488–0252.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons will serve on the CDC Performance Review Boards or Panels, which will oversee the evaluation of performance appraisals of Senior Executive Service members for the Fiscal Year 2018 review period:

Dean, Hazel Co-Chair
Shelton, Dana Co-Chair
Arispe, Irma
Boyle, Coleen
Branche, Christine
Curlee, Robert C.
Kosmos, Christine
Peeples, Amy
Qualters, Judith
Ruiz, Roberto
Smagh, Kalwant

Dated: September 17, 2018.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2018–20445 Filed 9–19–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4184–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2019

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2019. The calendar year 2019 AIC threshold amounts are $160 for ALJ hearings and $1,630 for judicial review.

DATES: This annual adjustment is effective for requests for ALJ hearings and judicial review filed on or after January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Liz Hosna (*Katherine.Hosna@cms.hhs.gov*), (410) 786–4993.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1869(b)(1)(E) of the Social Security Act (the Act), as amended by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), established the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review at $100 and $1,000, respectively, for Medicare Part A and Part B appeals. Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. Beginning in January 2005, the AIC threshold amounts are to be adjusted by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to Medicare Part C/Medicare Advantage (MA) appeals and certain health maintenance organization and competitive health plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.

A. Medicare Part A and Part B Appeals

The statutory formula for the annual adjustment to the AIC threshold amounts for ALJ hearings and judicial review of Medicare Part A and Part B appeals, set forth at section 1869(b)(1)(E) of the Act, is included in the applicable implementing regulations, 42 CFR 405.1006(b) and (c). The regulations require the Secretary of Health and Human Services (the

Secretary) to publish changes to the AIC threshold amounts in the **Federal Register** (§ 405.1006(b)(2)). In order to be entitled to a hearing before an ALJ, a party to a proceeding must meet the AIC requirements at § 405.1006(b). Similarly, a party must meet the AIC requirements at § 405.1006(c) at the time judicial review is requested for the court to have jurisdiction over the appeal (§ 405.1136(a)).

B. Medicare Part C/MA Appeals

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Medicare Part C appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C appeals are found at 42 CFR 422, subpart M. Specifically, §§ 422.600 and 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 422.600 grants any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsideration determination a right to an ALJ hearing as long as the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary. Section 422.612 states, in part, that any party, including the MA organization, may request judicial review if the AIC meets the threshold requirement established annually by the Secretary.

C. Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Section 1876(c)(5)(B) of the Act states that the annual adjustment to the AIC dollar amounts set forth in section 1869(b)(1)(E)(iii) of the Act applies to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals are set forth in 42 CFR 422, subpart M and apply to these appeals in accordance with 42 CFR 417.600(b). The Medicare Part C appeals rules also apply to health care prepayment plan appeals in accordance with 42 CFR 417.840.

D. Medicare Part D (Prescription Drug Plan) Appeals

The annually adjusted AIC threshold amounts for ALJ hearings and judicial review that apply to Medicare Parts A, B, and C appeals also apply to Medicare Part D appeals. Section 101 of the MMA added section 1860D–4(h)(1) of the Act regarding Part D appeals. This statutory provision requires a prescription drug plan sponsor to meet the requirements set forth in sections 1852(g)(4) and (g)(5) of the Act, in a similar manner as MA organizations. As noted previously, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) of the Act by section 940(b)(2)(A) of the MMA. The implementing regulations for Medicare Part D appeals can be found at 42 CFR 423, subparts M and U. The regulations at § 423.562(c) prescribe that, unless the Part D appeals rules provide otherwise, the Part C appeals rules (including the annually adjusted AIC threshold amount) apply to Part D appeals to the extent they are appropriate. More specifically, §§ 423.1970 and 423.1976 of the Part D appeals rules discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 423.1970(a) grants a Part D enrollee, who is dissatisfied with the independent review entity (IRE) reconsideration determination, a right to an ALJ hearing if the amount remaining in controversy after the IRE reconsideration meets the threshold amount established annually by the Secretary. Sections 423.1976(a) and (b) allow a Part D enrollee to request judicial review of an ALJ or Medicare Appeals Council decision if, in part, the AIC meets the threshold amount established annually by the Secretary.

II. Provisions of the Notice—Annual AIC Adjustments

A. AIC Adjustment Formula and AIC Adjustments

As previously noted, section 940 of the MMA requires that the AIC threshold amounts be adjusted annually, beginning in January 2005, by the percentage increase in the medical care component of the CPI for all urban consumers (U.S. city average) from July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10.

B. Calendar Year 2019

The AIC threshold amount for ALJ hearings will remain at $160 and the AIC threshold amount for judicial review will rise to $1,630 for CY 2019. These amounts are based on the 63.035 percent increase in the medical care component of the CPI, which was at 297.600 in July 2003 and rose to 485.193 in July 2018. The AIC threshold amount for ALJ hearings changes to $163.04 based on the 63.035 percent increase over the initial threshold amount of $100 established in 2003. In accordance with section 1869(b)(1)(E)(iii) of the Act, the adjusted threshold amounts are rounded to the nearest multiple of $10. Therefore, the CY 2019 AIC threshold amount for ALJ hearings is $160.00. The AIC threshold amount for judicial review changes to $1,630.35 based on the 63.035 percent increase over the initial threshold amount of $1,000. This amount was rounded to the nearest multiple of $10, resulting in the CY 2019 AIC threshold amount of $1,630.00 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2015 through 2019 threshold amounts.

	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019
ALJ Hearing	$150	$150	$160	$160	$160
Judicial Review	1,460	1,500	1,560	1,600	1,630

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 31, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–20506 Filed 9–19–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of New Matching Program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is providing notice of a new computer matching program between CMS and the Department of Homeland Security (DHS)/United States Citizenship and Immigration Services (USCIS), ''Verification of United States Citizenship and Immigration Status Data for Eligibility Determinations.'' In this matching program, DHS/USCIS provides CMS with immigrant, nonimmigrant, and naturalized or derived citizenship status information needed to make enrollment and exemption eligibility determinations as required by the Patient Protection and Affordable Care Act (ACA).

DATES: The deadline for comments on this notice is October 22, 2018. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately October 2018 to April 2020) and within 3 months of expiration may be renewed for one additional year if the parties make no change to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit comments on the new matching program to the CMS Privacy Officer by mail at: Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850, or *walter.stone@cms.hhs.gov.* Comments received will be available for review without redaction unless otherwise advised by the commenter at this location, by appointment, during regular business hours, Monday through Friday from 9:00 a.m. to 3:00 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact Jack Lavelle, Senior Advisor, Marketplace Eligibility and Enrollment Group, Centers for Consumer Information and Insurance Oversight, CMS, at (410) 786–0639, by email at *Jack.Lavelle1@cms.hhs.gov,* or by mail at 7501 Wisconsin Ave., Bethesda, MD 20814.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a) provides certain protections for individuals applying for and receiving federal benefits. The law governs the use of computer matching by federal agencies when records in a system of records (meaning, federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other federal or non-federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o) (2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopulos,

CMS Privacy Advisor, Division of Security, Privacy Policy and Governance, Information Security and Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services.

PARTICIPATING AGENCIES:

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Department of Homeland Security (DHS), United States Citizenship and Immigration Services (USCIS) is the source agency.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

The statutory authority for the matching program is 42 U.S.C. 18001.

PURPOSE(S):

The matching program will provide CMS with USCIS data, including immigrant, nonimmigrant, and naturalized or derived citizenship status information from USCIS's SAVE program and VIS system. This data will indicate whether an applicant or enrollee is lawfully present, a qualified non-citizen, a naturalized or derived citizen, and whether the five-year waiting period for many non-citizens applies and has been met. CMS and state administering entities will use the data to determine the individual's eligibility for enrollment in a qualified health plan through a federally-facilitated exchange (FFE) and for insurance affordability programs and certificates of exemption, and to make eligibility redetermination and renewal decisions, including appeal determinations. USCIS will provide the data from USCIS's SAVE program and VIS system about individuals whose identifying information matches identifying information that CMS submits to USCIS. CMS will make the USCIS data available to requesting state administering entities through a data services hub (Hub).

CATEGORIES OF INDIVIDUALS:

The individuals whose information will be used in the matching program are consumers who apply for any of the following eligibility determinations: eligibility to enroll in a qualified health plan through an exchange established under the ACA, eligibility for insurance affordability programs and certificates of exemption, and subsequent eligibility redeterminations and renewals, including appeal determinations

CATEGORIES OF RECORDS:

The categories of records used in the matching program are identity and citizenship status records. The data elements are described below.

- *From the CMS to USCIS.* CMS will submit data elements pertaining to applicants and enrollees through SAVE to the USCIS VIS. These data elements may include the following: identification number (*e.g.,* foreign passport number, I–94 number, alien registration number/USCIS number); immigration document type; last name; middle initial; first name; date of birth; document expiration date (if applicable); and information contained in the comment field, such as USCIS benefit application receipt numbers, maiden names, nicknames, and additional immigration document numbers.
- *From USCIS to CMS.* USCIS through SAVE will send the Hub responses that contain data from records provided to VIS and databases VIS accesses. These responses may include

the following data elements: alien registration number/USCIS number; I–94 number; last name; first name; date of birth; date of entry; status grant date, if available; and immigration status data.

SYSTEM OF RECORDS:

The records used in this matching program are disclosed from the following systems of records, as authorized by routine uses published in the System of Records Notices (SORNs) cited below:

A. CMS System of Records:

• CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018). Routine use 3 supports CMS's disclosures to USCIS.

B. USCIS System of Records:

• DHS/USCIS–004 Systematic Alien Verification for Entitlements Program, 81 FR 78619 (Nov. 8, 2016). Routine use H permits USCIS' disclosures to CMS.

[FR Doc. 2018–20510 Filed 9–19–18; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6526]

Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; 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 ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' This guidance specifies whether and under what circumstances packages and homogenous cases of product not labeled with a product identifier shall be grandfathered from certain requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance finalizes the draft guidance issued on November 27, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6526 for ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Abha Kundi, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) was signed into law. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee–1), which established product tracing requirements for manufacturers, repackagers, wholesale distributors, and dispensers. The DSCSA phases in its requirements over a 10-year period.

A critical set of phased product tracing requirements outlined in section 582 of the FD&C Act relates to the product identifier. Among its provisions, section 582 of the FD&C Act requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product's standardized numerical identifier, lot number, and expiration date by specific dates. Under the statute, manufacturers were required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced into commerce no later than November 27, 2017. Repackagers are required to do the same no later than November 27, 2018.

Sections 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the FD&C Act restrict trading partners' ability to engage in transactions involving packages and homogenous cases of product that are not labeled with a product identifier after specific dates. Beginning November 27, 2018, repackagers may not engage in a transaction involving a package or homogenous case of a product that is not encoded with a product identifier. Similar restrictions go into effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020, respectively.

In addition, section 582 of the FD&C Act requires trading partners to verify product identifiers on packages and homogenous cases starting on November 27, 2017, for manufacturers (section 582(b)(4)); on November 27, 2019, for wholesale distributors (section 582(c)(4)); on November 27, 2020, for dispensers (section 582(d)(4)); and on November 27, 2018, for repackagers (section 582(e)(4)). Manufacturers, repackagers, wholesale distributors, and dispensers are also required to verify the product identifier of a saleable returned package or sealed homogenous case on November 27, 2017, November 27, 2018, November 27, 2019, and November 27, 2020, respectively.

In section 582(a)(5)(A) of the FD&C Act, Congress directed FDA to issue guidance specifying ''whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical supply chain at the time at the time of the effective date of the requirements of [section 582] shall be exempted'' from the product tracing requirements discussed previously. The guidance addresses this requirement. As explained in the guidance, only packages and homogenous cases of product that are in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of section 582 are eligible for grandfathering under section 582(a)(5)(A) of the FD&C Act.

In the **Federal Register** of November 27, 2017 (82 FR 56033), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period for the draft guidance ended January 26, 2018. FDA received approximately 10 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. The most significant change FDA made was to revise the grandfathering exemption to include products repackaged by a repackager before November 27, 2018. FDA made this change in response to comments indicating that repackagers will need time beyond November 27, 2018, to sell such product. In addition, FDA made editorial and formatting changes to improve clarity.

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 ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' It does not establish any rights for any person and, with the exception of specified material in section IV, 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 *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: September 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20503 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2167]

Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing; Guidance for Industry and Food and Drug Administration Staff; 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 ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' The United States Pharmacopeia (USP) drug substance monograph for Heparin Sodium, and drug product monographs for Heparin Lock Flush Solution and Heparin Sodium Injection, recently have undergone several revisions following serious and fatal events related to the use of heparin sodium products. Investigation of heparin product overdose errors identified the expression of drug strength in the labels as a major contributing factor in these errors. This guidance document addresses these safety concerns by clarifying new expectations for labeling with regard to the revised heparin USP monographs, as well as outlining safety testing recommendations.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–2167 for ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Andrew Yeatts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20993–0002, 301–796–4539.

SUPPLEMENTARY INFORMATION:

I. Background

The USP [1] heparin monographs have recently undergone several revisions following serious and fatal events related to the use of heparin sodium products. Investigation of heparin product overdose errors identified the expression of drug strength in the labels as a major contributing factor in these errors. This guidance document addresses these safety concerns by clarifying new expectations for labeling with regard to the revised heparin USP monographs, as well as outlining safety testing recommendations.

In addition, the outbreak of serious and often fatal events due to heparin contamination with over-sulfated chondroitin sulfate in 2008 led the USP to include in its monograph additional testing of heparin source material to ensure its quality and purity. This guidance also outlines use of conformance to the monograph in premarket submissions, specifically testing and documentation requirements and/or recommendations contained in the current USP monographs and the guidance document ''Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality'' (*https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291390.pdf*).[2]

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of July 9, 2015 (80 FR 39440). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

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 ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This

[1] USP is a scientific nonprofit organization that develops standards for the identity, strength, quality, and purity of drugs and drug ingredients marketed in the United States. These standards are published in USP's official compendia, U.S. Pharmacopeia and National Formulary.

[2] The Agency updates guidances periodically. To make sure you have the most recent version of this guidance, check the FDA guidance page at *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.*

guidance is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1817 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
211	Current good manufacturing practice for finished pharmaceuticals	0910–0139
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
801	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Quality System (QS) Regulation	0910–0073

Dated: September 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20472 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2232]

Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy; 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 ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' This guidance describes FDA's intention with regard to enforcement of the Drug Supply Chain Security Act (DSCSA) provision requiring manufacturers to begin affixing or imprinting product identifiers on their products beginning November 27, 2017. This guidance finalizes the draft guidance issued on July 3, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on September 20, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency Guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2017–D–2232 for ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' On November 27, 2013, the DSCSA (Title II of Pub. L. 113–54) was signed into law. Section 202 of the DSCSA added section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1) which established product tracing, product identifier, authorized trading partner and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Among its provisions, section 582 of the FD&C Act requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product's standardized numerical identifier, lot number, and expiration date by specific dates. Under the statute, manufacturers were required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced into commerce no later than November 27, 2017. Failure to comply with this and other requirements of section 582 is prohibited under section 301(t) of the FD&C Act (21 U.S.C. 331(t)) and subject to enforcement action under the FD&C Act.

In the **Federal Register** of July 3, 2017 (82 FR 30868), FDA issued a notice announcing the availability of the draft version of this guidance. As described in the guidance, in the years since the passage of DSCSA, FDA had received comments and feedback from manufacturers and other trading partners expressing concern with industry-wide readiness for implementation of the DSCSA provision requiring manufacturers to begin putting product identifiers on their products by November 27, 2017. Given the implementation challenges that industry has encountered, FDA recognized that some manufacturers would need additional time beyond November 27, 2017, to ensure that their products bear a product identifier as required by the DSCSA. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to packages or homogenous cases of product that are packaged before November 27, 2018. This includes packages and homogenous cases of product that are packaged by a manufacturer on or after November 27, 2017. The comment period for the draft guidance ended September 1, 2017. FDA received 19 comments on the draft guidance.

FDA made several changes to the guidance. We streamlined the guidance to remove information that is portions of the draft version of this guidance because they were repetitive of the information in the final guidance for industry entitled, ''Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.'' In addition, FDA removed the language in the draft version of this guidance on wholesale distributor and dispenser responsibilities to ensure product purchased from repackagers after November 27, 2018, is affixed or imprinted with a product identifier. Finally, FDA removed the recommendations in the draft version of this guidance related to the documentation for determining when a product without a product identifier was introduced in a transaction into commerce by a manufacturer. The topic of documentation is addressed in the final grandfathering policy guidance.

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 ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy.'' 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 *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov*.

Dated: September 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20444 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3175]

Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers.'' This draft guidance intends to clarify questions relating to product identifiers that are required by the Federal Food, Drug, and Cosmetic Act

(FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA) for packages and homogenous cases of certain drug products. Sections of the FD&C Act require manufacturers and repackagers to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce beginning November 27, 2017, and November 28, 2018, respectively. This draft guidance intends to clarify these requirements.

DATES: Submit either electronic or written comments on the draft guidance by November 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by November 19, 2018.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2018–D–3175 for ''Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tia Harper-Velazquez, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *CDERBarcodeQuestions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee–1). This section establishes product tracing, product identifier, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 is a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. 331(t)).

The effective date for manufacturers to ''affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce'' under section 582(b)(2)(A) of the FD&C Act, is not later than November 27, 2017. In June 2017, FDA published a draft guidance entitled ''Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy,'' in which FDA describes its intention regarding the enforcement of certain product identifiers under the DSCSA. As described in the draft guidance, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of products intended to be introduced in a transaction into commerce before November 26, 2018. This represents a 1-year delay in enforcement of the requirement for manufacturers to affix or imprint product identifiers. The

effective date for repackagers to ''affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in commerce'' under section 582(e)(2)(A) of the FD&C Act, is not later than November 27, 2018.

This guidance is intended to assist manufacturers and repackagers in understanding the requirements to affix or imprint a product identifier on each package and homogenous case of product that they introduce in a transaction into commerce to satisfy the product identifier requirement of section 582 of the FD&C Act. The recommendations in this guidance are intended to assist manufacturers and repackagers in standardizing both the human-readable and machine-readable format of the information that is contained in the product identifier. This guidance also intends to clarify that these requirements do not change the linear barcode requirements.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Product Identifiers Under the Supply Chain Security Act Questions and Answers.'' 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 includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520) (PRA). In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20502 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about the ACHDNC, a roster of members, the meeting agenda, as well as past meeting summaries is located on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: November 1, 2018, 10:30 a.m.–5:30 p.m. ET and November 2, 2018, 9:00 a.m.–3:00 p.m. ET.

ADDRESSES: This meeting will be held in person and by webinar. Advanced registration is required. Please register online at *http://www.achdncmeetings.org/* by 12:00 p.m. ET on October 29, 2018. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18N100C, Rockville, Maryland 20857; 301–443–3999; or *AFerrero@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the November meeting, the ACHDNC will hear from experts in the field and discuss issues related to newborn screening information, education, training activities, and training resources. The ACHDNC will hear presentations on the use of genomic sequencing in newborn screening as well as the clinical setting for both well and sick infants. The ACHDNC will also discuss the nomination of cerebrotendinous xanthomatosis (CTX) to the RUSP and vote on whether to move the nomination forward to evidence review. Note that this vote is not on a proposed addition of a condition to the RUSP. Agenda items are subject to change as priorities dictate. Refer to the ACHDNC website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments, which are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on October 26, 2018, at *http://www.achdncmeetings.org.* Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.,* parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Ann Ferrero at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizens attendees planning to attend must notify HRSA of their planned attendance at least 10 business days prior to the meeting in

order to facilitate their entry into the building. Contact Ann Ferrero using the information mentioned above by Thursday, October 18, 2018, 12:00 p.m. ET. All attendees are required to present government-issued identification prior to entry. The meeting will also be accessible via webcast. Instructions on how to access the meeting via webcast will be provided upon registration.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–20428 Filed 9–19–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

Name of Committee: National Cancer Institute Council of Research Advocates.

Date: October 19, 2018.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: Welcome and Chairman's Remarks, NCI Updates, Legislative Update, Budget Update, and Director's Update.

Place: National Institutes of Health, 35A Convent Drive, Building 35A, 640, Bethesda, MD 20892.

Contact Person: Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 240–781–3360 *williaam@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NCRA: *http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 14, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20418 Filed 9–19–18; 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 is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Barry Buchbinder, Ph.D., 240–627–3678; *barry.buchbinder@nih.gov.* Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at 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 patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Glycan-Masked Engineered Outer Domains of HIV-1 GP120 and Their Use

Description of Technology:

The VRC01-class of potent, broadly neutralizing antibodies (bnAbs) targets the conserved CD4-binding site (CD4bs) of HIV-1 Env which has been a major target of HIV-vaccine design. The current best priming immunogen to engage the VRC01-class germline precursors is the eOD-GT8 60mer, which elicits VRC01-class precursors in multiple transgenic mouse models. However, a large proportion of the antibodies elicited by eOD-GT8 60mer are non-CD4bs or ''off-target'' antibodies, undermining its effectiveness in eliciting the VRC01-class bnAb precursors.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases introduced multiple N-linked glycosylation sites to mask non-CD4bs regions of eOD-GT8 60mer to focus the antibody immune response to the CD4bs.

Several glycan-masked mutants showed significantly decreased antibody binding to non-CD4bs ''off-target'' epitopes while maintaining strong binding to CD4bs-specific bnAbs. Furthermore, in vivo studies showed that immunization with the best glycan-masked eOD-GT8 mutants resulted in significant increases in the elicitation of CD4bs-specific serum antibodies, CD4bs-specific B cells in the spleen, and VRC01-class precursors, compared to immunization with the parental eOD-GT8 immunogen. In conclusion, because of their improved antigenic and immunogenic profiles, glycan-masked eOD-GT8 60mer mutants may serve as improved priming immunogens to elicit VRC01-class bnAbs in humans.

Potential Commercial Applications:

- HIV-1 vaccine—the priming component in a prime-boost approach.

Competitive Advantages:

- Reduced off-target immunogenicity.
- Improved efficacy in eliciting precursors for broadly neutralizing CD4bs antibodies.
- Facilitates the development of VRC01-class bnAbs in humans.

Development Stage: In vivo testing (rodents).

Inventors: John R. Mascola (NIAID), Hongying Duan (NIAID), Xuejun Chen (NIAID), Cheng Cheng (NIAID) and Jeffrey C. Boyington (NIAID).

Publications: Duan, H. et al., Glycan Masking Focuses Immune Responses to the HIV-1 CD4-Binding Site and Enhances Elicitation of VRC01-Class Precursor Antibodies. *Immunity* 49, 301 (2018).

Intellectual Property: HHS Reference Number E–083–2017 includes U.S. Provisional Patent Application Number 62/476,397 filed 03/24/2017 and PCT

Application Number PCT/US2018/024330 filed 03/26/2018.

Licensing Contact: Barry Buchbinder, Ph.D., 240–627–3678; *barry.buchbinder@nih.gov.*

Dated: September 10, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–20484 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed 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 section 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; DPBRN ARC.

Date: November 14, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Guo He Zhang, MPH, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 672, Bethesda, MD 20892, *zhanggu@mail.nih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; DPBRN Coordinating Center.

Date: November 14, 2018.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Guo He Zhang, MPH, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 672, Bethesda, MD 20892, *zhanggu@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 14, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20424 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Centers of Excellence for Translational Research (CETR) (U19).

Date: October 11–12, 2018.

Time: 8:00 a.m. to 6:00 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: Yong Gao, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities, Room #3G13B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–7616, (240) 669–5048, *yong.gao@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 14, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20421 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular Genetics B Study Section, September 27, 2018, 10:00 a.m. to September 28, 2018, 06:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on September 06, 2018, 83FR173 pg. 45264.

The meeting will be held on September 27, 2018, starting at 8:30 a.m. The meeting location remains the same. The meeting is closed to the public.

Dated: September 14, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20415 Filed 9–19–18; 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: October 3–4, 2018.

Time: 8:00 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: 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: Center for Scientific Review Special Emphasis Panel; PAR–15–357: Understanding Alzheimer's Disease in the Context of the Aging Brain.

Date: October 3, 2018.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biostatistical Methods and Research Design.

Date: October 4, 2018.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, *wieschd@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

Date: October 11–12, 2018.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Baltimore, 2 N Charles, Baltimore, MD 21201.

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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroimmunology and Brain Tumors Study Section.

Date: October 11–12, 2018.

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: Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7846, Bethesda, MD 20892–7846, 301–435–1236, *zhaow@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: October 11, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301–435–0904, *sara.ahlgren@nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

Date: October 15–16, 2018.

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: Cell Biology Integrated Review Group; Development—2 Study Section.

Date: October 15–16, 2018.

Time: 8:00 a.m. to 12:00 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: 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Brain Injury and Neurovascular Pathologies Study Section.

Date: October 15–16, 2018.

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: Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Chronic Dysfunction and Integrative Neurodegeneration Study Section.

Date: October 15–16, 2018.

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: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Societal and Ethical Issues in Research.

Date: October 15, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Seattle Downtown Pioneer Square, 612 2nd Avenue, Seattle, WA 98104.

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301–254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Cell Biology Study Section.

Date: October 15–16, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–408–9850, *morrowcs@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: October 15–16, 2018.

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: Alexey Belkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, Bethesda, MD 20817, 301–435–1786, *alexey.belkin@nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Vector Biology Study Section.

Date: October 15–16, 2018.

Time: 8:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street NW, Washington, DC 20037.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, *zhengli@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Clinical Research and Field Studies of Infectious Diseases Study Section.

Date: October 15–16, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Chicago West Loop, 733 West Madison, Chicago, IL 60661.

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.*

(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: September 14, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20413 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review of Support of Competitive Research (SCORE) Award Applications.

Date: November 2, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: Cambria Suites Rockville, 1 Helen Heneghan Way, Rockville, MD 20850.

Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.22, Bethesda, MD 20892–6200, 301–402–9448, *shinako.takada@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 14, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20425 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Regulatory Science—Basic Science.

Date: October 2, 2018.

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: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Dissemination and Implementation Research in Health Study Section.

Date: October 10–11, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Capitol Skyline Hotel, 10 I St. SW, Washington, DC 20024.

Contact Person: Yvonne Owens Ferguson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301–827–3689, *fergusonyo@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–17–094: Maximizing Investigators' Research Award (R35).

Date: October 10, 2018.

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: Maqsood A. Wani, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114, MSC 7814, Bethesda, MD 20892, 301–435–2270, *animaqs@csr.nih.gov*.

Name of Committee: Cell Biology Integrated Review Group; Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

Date: October 11, 2018.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy Washington DC Bethesda North, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *jessica.smith6@nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: October 11–12, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave. NW, Washington, DC 20037.

Contact Person: Fungai Chanetsa, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Clinical Molecular Imaging and Probe Development.

Date: October 11–12, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA 22311.

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Neurological, Aging and Musculoskeletal Epidemiology Study Section.

Date: October 11–12, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn by Marriott Arlington Pentagon City, 550 Army Navy Dr., Arlington, VA 22202.

Contact Person: Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–435–1721, *hfriedman@csr.nih.gov*.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Molecular and Cellular Endocrinology Study Section.

Date: October 11–12, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Liliana Norma Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4215, Bethesda, MD 20892, *liliana.berti-mattera@nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Community-Level Health Promotion Study Section.

Date: October 15–16, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Georgetown, 2350 M Street, NW, Washington, DC 20037.

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–451–8428 *wup4@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–GM–18–002: Training Modules to Enhance the Rigor and Reproducibility of Biomedical Research (R25).

Date: October 16, 2018.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Vonda K. Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301–435–1789, *smithvo@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: September 14, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20414 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; State-of-the-Art Functional MRI Approaches Combined with MVPA (9916).

Date: October 4, 2018.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 827–5702, *lf33c.nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Assessment of Potential Substance Abuse Treatment Medications in Nonhuman Primate Models (8946).

Date: October 18, 2018.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 827–5702, *f33c.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 14, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20417 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting Microbiology, Infectious Diseases and AIDS Initial Review Group Microbiology and Infectious Diseases Research Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases Research Committee.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Program, Division of Extramural Activities, SRP, RM 3G51 National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852–9823, 301–496–2550, *amir.zeituni@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 14, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20422 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Exploiting Omics Assays to Investigate Molecular Regulation of Persistent HIV in

Individuals with Substance Use Disorder (R61/R33 Clinical Trial Optional).

Date: October 3, 2018.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, *ramadanir@mail.nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Exploring Epigenomic or Non-Coding RNA Regulation in the Development, Maintenance, or Treatment of Chronic Pain (R61/R33 Clinical Trial Optional).

Date: October 12, 2018.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, *ramadanir@mail.nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Coordinating Center to Support NIDA Rural Opioid HIV and Comorbidity Initiative (U24—Clinical Trial Not Allowed).

Date: October 17, 2018.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 14, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20423 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Institutional Training Grants.

Date: October 17, 2018.

Time: 9:00 a.m. to 1:00 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: Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *firthkm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 14, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20420 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of New NIH Policy Manual 1311—Preventing and Addressing Harassment and Inappropriate Conduct and New Policy Statement on Inappropriate Relationships in the Workplace

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) announces Policy Manual Chapter: 1311—Preventing and Addressing Harassment and Inappropriate Conduct and a new Policy Statement addressing Personal Relationships in the Workplace. These policies apply to federal employees, contractors, trainees, and fellows who perform work for the NIH. The NIH expects that organizations receiving NIH funds have in place similarly rigorous policies and related procedures for their employees, contractors, trainees, and fellows who engage in agency-funded activities.

FOR FURTHER INFORMATION CONTACT: For further information about these new policies, contact Jessica Hawkins, Office of Human Resources, National Institutes of Health, Building 31, Room 1/B37, Bethesda, Maryland 20892, telephone 301–402–8006 (not a toll-free number), *hawkinj@od.nih.gov.*

SUPPLEMENTARY INFORMATION: Policy Manual 1311—Preventing and Addressing Harassment and Inappropriate Conduct states that the NIH will not tolerate inappropriate conduct or harassment, including sexual harassment. Timely and appropriate action will be taken against any individual found to be in violation of the policy outlined in the Manual Chapter. Through enforcement of this policy, the NIH seeks to prevent, correct, and eliminate unacceptable behavior that is inconsistent with the values and culture of respect and inclusion. Further, the policy is intended to increase the transparency and consistency in how allegations of harassment are reviewed and resolved. NIH leadership has designated the Office of Human Resources' Civil Program as the entity charged with receiving allegations of harassment and overseeing relevant administrative inquiries.

The NIH Policy Statement on Personal Relationships in the Workplace states that personal relationships (including romantic and/or sexual) between individuals in inherently unequal positions, where one party has real or perceived authority over the other in their professional roles, may be inappropriate in the workplace and are strongly discouraged. If such a relationship exists or develops, it must be disclosed. Upon such notification, the responsible agency official must insure that the NIH Institute/Center manages, decreases, or eliminates potential risk as a result of the relationship.

This applies to all individuals in the NIH community, including employees, contractors, students, trainees, and fellows and includes anyone who holds a position of authority or perceived

authority over another individual from a scientific or administrative perspective.

Dated: September 17, 2018.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2018–20505 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Innovative Molecular and Cellular Analysis Technologies (IMAT).

Date: October 19, 2018.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 2E908, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W114, Bethesda, MD 20892–9750, 240–276–5287, *decluej@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Systems Biology.

Date: November 1, 2018.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 5335 Wisconsin Ave. NW, Washington, DC 20015.

Contact Person: Eun Ah Cho, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W124, Bethesda, MD 20892–9750, 240–276–6342, *choe@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Investigation of the Transmission of Kaposi Sarcoma-Associated Herpesvirus.

Date: November 14, 2018.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Byeong-Chel Lee, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W238, Bethesda, MD 20892–9750, 240–276–7755, *byeong-chel.lee@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 14, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20419 Filed 9–19–18; 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: Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301–435–2204, *girouxcn@csr.nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

Date: October 18, 2018.

Time: 8:00 a.m. to 6:00 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: Bukhtiar H Shah, DVM, Ph.D., Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Host Interactions with Bacterial Pathogens Study Section.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Warwick Denver, 1776 Grant Street, Denver, CO 80203.

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, *elzaataf@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: October 18–19, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: October 18–19, 2018.

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: Mary Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301–451–0996, *marygs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Behavioral Neuroscience.

Date: October 18–19, 2018.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites DC Convention Center, 900 10th Street NW, Washington, DC 20001.
Contact Person: Mei Qin, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301–875–2215, *qinmei@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.
Date: October 18–19, 2018.
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: Sussan Paydar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 5222, Bethesda, MD 20817, (301) 827–4994, *sussan.paydar@nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Developmental Brain Disorders Study Section.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue NW, Washington, DC 20036.
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: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Somatosensory and Pain Systems Study Section.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Hotel & Suites, 625 First Street, Alexandria, VA 22314.
Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: John Burch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301–408–9519, *burchjb@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Biomarkers Study Section.
Date: October 18–19, 2018.
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: Lawrence Ka-Yun Ng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7804, Bethesda, MD 20892, 301–357–9318, *ngkl@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Drug Discovery for the Nervous System Study Section.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites Alexandria Old Town, 1900 Digonal Road, Alexandria, VA 22314.
Contact Person: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Immunity and Host Defense Study Section.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.
Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–435–1506, *jakesse@mail.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Systemic Injury by Environmental Exposure.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.
Contact Person: Meenakshisundar Ananthanarayanan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, Bethesda, MD 20817, 301–435–1234, *ananth.ananthanarayanan@nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Clinical and Integrative Cardiovascular Sciences Study Section.
Date: October 18–19, 2018.
Time: 8:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Ave. NW, Washington, DC 20037.
Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, 301–435–1850, *limc4@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Clinical and Integrative Diabetes and Obesity Study Section.
Date: October 18–19, 2018.
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: Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1044, *chenhui@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies B Study Section.
Date: October 18, 2018.
Time: 8:30 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW, Washington, DC 20008.
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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Infectious Diseases.
Date: October 18, 2018.
Time: 3:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Neerja Kaushik-Basu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435–2306, *kaushikbasun@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Chemosensory Systems Study Section.
Date: October 19, 2018.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005.
Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Academic Research Enhancement Award.

Date: October 19, 2018.

Time: 1:00 p.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: Inna Gorshkova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1784, *gorshkoi@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: September 14, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20416 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council for Complementary and Integrative Health, October 5, 2018, 8:30 a.m. to October 5, 2018, 04:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892 which was published in the **Federal Register** on August 28, 2018, 83 FR167, page 43883.

This meeting notice is amended to change the starting time of the OPEN SESSION from 10:00 a.m. to 9:30 a.m. (EDT). The meeting is partially Closed to the public.

Dated: September 17, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20483 Filed 9–19–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: TSA Claims Application

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0039, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves the submission of information from claimants to examine and resolve tort claims against the agency.

DATES: Send your comments by October 22, 2018. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on May 10, 2018, at 83 FR 21788.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O.13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Title: TSA Claims Application.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0039.

Forms(s): Supplemental Information Form, Payment Form.

Affected Public: Members of the traveling public who believe they have experienced property loss or damage, a personal injury, or other damages due to the negligent or wrongful act or omission of a TSA employee within their scope of employment, and decide to seek compensation by filing a federal tort claim against TSA.

Abstract: The TSA Claims, Outreach, and Debt Branch adjudicates tort claims pursuant to the Federal Tort Claims Act (28 U.S.C. 1346(b), 1402(b), 2401(b), 2671–2680). OMB Control Number 1652–0039, TSA Claims Application, allows the agency to collect information from claimants to examine and resolve tort claims against the agency.

The claims branch has changed its name from Claims Management Branch to Claims, Outreach, and Debt Branch and is revising the information collection form by changing the name from ''TSA Claims Management Branch Program'' to ''TSA Claims Application.'' These changes provide the public with a better understanding of the operational functions conducted when a member of the traveling public files an SF–95, claims application.

TSA receives approximately 850 tort claims per month arising from airport screening activities, motor vehicle accidents, and employee loss, among others.

Number of Respondents: 10,200.

Estimated Annual Burden Hours: An estimated 5,300 hours.

Dated: September 14, 2018.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2018–20412 Filed 9–19–18; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6126–N–01]

Notice of Intent To Prepare a Draft Environmental Impact Statement for the Rose Hill Courts Redevelopment

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS).

SUMMARY: The City of Los Angeles, through the Housing and Community Development Investment Department (HCID), is providing notice of its intent to prepare a combined Environmental Impact Statement (EIS) in accordance with the National Environmental Policy Act (NEPA) and Environmental Impact Report (EIR) in accordance with the California Environmental Quality Act (CEQA) (EIR/EIS) for the Rose Hill Courts Redevelopment Project located in Los Angeles, CA. The proposed action is subject to compliance with NEPA because the Housing Authority of the City of the City of Los Angeles (HACLA) is proposing a HUD Section 18 demolition/disposition and the developer is planning to use Project Based Section 8 vouchers. HACLA will consider a Disposition and Development Agreement. This Notice of Intent to prepare an EIS represents the beginning of the public scoping process. Following the scoping meeting referenced below, a Draft EIS will be prepared and ultimately circulated.

ADDRESSES: Comments relating to the scope of the EIR/EIS are requested and will be accepted by the contact persons listed below until October 20, 2018. Any person or agency interested in receiving a notice and wishing to comment on the draft EIR/EIS should contact the persons listed below. Documents are available at the following website: *http://hcidla.lacity.org/NEPA-review.*

FOR FURTHER INFORMATION CONTACT: Dr. Robert Manford, Environmental Affairs Officer, Planning and Land Use, Finance & Development Division of the City of Los Angeles Housing, Community Investment Department, 1200 West 7th Street, 8th Floor, Los Angeles, CA 90017. Comments and questions can also be directed to *robert.manford@lacity.org,* Fax: (213) 808–8914, (NEPA) and Dhiraj Narayan, Development Officer, Development Services, HACLA, *RHCRedev.CEQA@hacla.org,* telephone number 213–252–6120, fax number 213–252–2739 (CEQA).

Public Participation: The public will be invited to participate in the review of the Draft EIR/EIS. Release of the Draft EIR/EIS will be announced through public mailings as well as the local news media. All interested Federal, state, and local agencies, Indian tribes, groups, and the public are invited to comment on the scope of the EIR/EIS. If you are an agency with jurisdiction by law over natural or other public resources affected by the project, HCID needs to know what environmental information germane to your statutory responsibilities should be included in the EIR/EIS.

SUPPLEMENTARY INFORMATION:

Project Name and Description

HCID will consider a proposal to redevelop the project site including new construction of 191 new affordable housing units, developed in two phases. Proposed improvements include 176 parking spaces, a new property management and maintenance office, and new landscaping. The project site is 5.24-acres in size and is located at 4446 Florizel Street in Los Angeles, California. The site slopes in a west to east direction by +/− 65 feet, and it is currently developed with a total of 15 buildings, comprised of 14 residential buildings with 100-multi-family units, and one administration building (*i.e.,* offices and a common room with a kitchen, pantry, and two bathrooms).

The project site is bounded by Florizel Street to the north; McKenzie Avenue to the east; Mercury Avenue to the south; and Boundary Avenue to the west. An onsite driveway, Victorine Street, runs in an east-west direction across the middle of the project bisecting the site into two parts: The northern part and the southern part.

Land uses surrounding the project site include the Ernest E. Debs Regional Park to the west, along Mercury Avenue and Boundary Avenue; Rose Hill Park to the north; the Rose Hill Recreation Center to the southeast. Our Lady of Guadalupe Catholic Church and Elementary School is located east of the project site, along Browne Avenue. Single-family and multi-family residential developments are located to the south and east.

The project would require the following discretionary approvals: (1) Disposition and Development Agreement approval from HACLA; (2) Grading and Building Permits from the City of Los Angeles Department of Building and Safety; (3) Public Benefits Project and Alternative Compliance approval from the Los Angeles Department of City Planning; (4) National Environmental Policy Act (NEPA) Part 58 Compliance necessary for Demolition/Disposition and Rental Assistance Demonstration (RAD) Conversion of the existing Rose Hill Courts development to Section 8 Project Based Vouchers from the United States Department of Housing and Urban Development (HUD); (5) Certification of the Environmental Impact Report/Environmental Impact Statement; (6) Haul route approval from the Los Angeles Department of Building and Safety (if required); (7) Permit for removal of street trees from the Los Angeles Board of Public Works (if required); and (8) Other discretionary and ministerial permits and approvals that may be deemed necessary, including, but not limited to, temporary street closure permits, grading permits, excavation permits, foundation permits, building permits, and sign permits in order to execute and implement the Project.

This is to be a combined environmental document, an EIR, prepared under the State of California CEQA (Public Resources Code 21000 *et seq.* and 14 California Code of Regulations 15000 *et seq.*), and an EIS, prepared under NEPA (42 U.S.C. 4321) and implementing regulations of the Council on Environmental Quality (40 CFR parts 1500–1508) and HUD (24 CFR part 58).

The Project involves funding from HUD that qualifies as an ''undertaking'' subject to the Programmatic Agreement (PA) Among the City of Los Angeles, the California State Historic Preservation Officer, and the Advisory Council on Historic Preservation Regarding Historic Properties Affected by use of Community Development Block Grants; McKinney Act Homeless Programs including the Emergency Shelter Grants Program, Transitional Housing, Permanent Housing for the Homeless Handicapped, and Supplemental Assistance for Facilities to Assist the Homeless; Home Investment Partnership Funds, and the Shelter Plus Care Program for compliance with 36 CFR part 800, the regulations implementing Section 106 of the National Historic Preservation Act. HCID will be initiating the Section 106 consultation process with the SHPO through the PA.

The project proposes the demolition of all 15 buildings at Rose Hill Courts and subsequent construction of 191 affordable public housing units. Rose

Hill Courts was constructed in 1942 by HACLA as a low-income public housing project. Rose Hill Courts was determined eligible for listing in the National Register of Historic Places. The Rose Hill Courts complex is located at 4446 Florizel Street, on a 5.24-acre site. The site is located within the Northeast Los Angeles Community Plan, in the Rose Hills neighborhood area of the City of Los Angeles.

Alternatives to the Proposed Action

The EIR/EIS will discuss the alternatives that were considered for analysis, identify those that were eliminated from further consideration because they do not meet the stated purpose and need, and identify those that will be analyzed further. It is expected that project alternatives will continue to be developed and refined during the public scoping process, with input from the public, agencies, and other stakeholders. The EIR/EIS alternatives analysis will consist of a comparison of the impacts under each alternative pursuant to 24 CFR part 58, in addition to how well each alternative achieves the project's purpose and need. This process, which will be described in detail in the EIR/EIS, will lead to the designation of a Preferred Alternative.

At this time, it is anticipated that the following alternatives will be analyzed: (1) No Project/No Action Alternative; (2) Non-Historically Compliant Rehabilitation Alternative; and (3) Historic Rehabilitation.

1. No Project/No Action Alternative. This alternative would be the continuation of uses on the site; therefore, existing buildings and tenants would remain at the project site and no buildings or uses would be constructed or demolished.

2. Non-Historically Compliant Rehabilitation Alternative. This alternative would redevelop the existing units at Rose Hill Courts but not in a way that would preserve their historic integrity. However, the Non-Historically Compliant Rehabilitation Alternative would retain the existing 100 units on the project site and would not allow for the opportunity to increase the number of affordable housing units on the project site.

3. Historic Rehabilitation. This alternative would redevelop the existing units at Rose Hill Courts in a way that would preserve the historic integrity of the buildings. This alternative would restore the characteristics of the Garden Style design utilized in the Rose Hill Courts development, including but not limited to low-slung buildings, large open spaces, and recreational amenities.

Probable Environmental Effects

The following subject areas will be analyzed in the combined EIR/EIS for probable environmental effects: Aesthetics, Air Quality, Biological Resources, Cultural Resources, Geology and Soils, Greenhouse Gas Emissions, Hazards and Hazardous Materials, Land Use and Planning, Noise, Population and Housing, Public Services, Recreation, Transportation/Traffic, and Tribal Cultural Resources.

Scoping Meeting

A public scoping meeting will be held from 5:00 p.m. to 7:00 p.m. on October 4, 2018, at the Rose Hill Courts Community Center at 4446 Florizel Street, Los Angeles, California. The scoping process also includes the initiation of the NHPA Section 106 consultation process. We invite comments from all interested parties about the potential impacts this project may have on historic properties, cultural resources, or biological and natural resources as well as the impacts these resources may have on the project. We invite all interested parties to participate in the scoping meeting.

Lead Agencies

HCID is the responsible entity (RE) and lead agency for this project in accordance with 24 CFR part 58, ''Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities.'' As a RE, the HCID assumes the responsibility for environmental review, decision-making, and action that would otherwise apply to HUD under NEPA. Section 26 of the United States Housing Act (42 U.S.C. 1437x) allows units of general local government to assume NEPA responsibilities in projects involving Section 18 demolition/disposition and Section 8 Project-Based Vouchers. The project may use CDBG and HOME funds. If so, Section 104(g) of the Housing and Community Development Act of 1974 (42 U.S.C. 5304(g)) and Section 288 of the HOME Investment Partnerships Act (42 U.S.C. 12838) allow CDBG recipients and HOME jurisdictions, respectively, to assume NEPA responsibilities for CDBG and HOME projects.

In addition, the HACLA is the CEQA lead agency and is responsible for preparing an EIR. Questions may be directed to the individuals named in this notice under the heading **FOR FURTHER INFORMATION CONTACT**.

Dated: September 14, 2018.

Neal J. Rackleff,

Assistant Secretary.

[FR Doc. 2018–20514 Filed 9–17–18; 4:15 pm]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLES930000.L51040000.FI0000. 18X]

Notice of Proposed Reinstatement of Terminated Oil and Gas Leases in Ohio

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of reinstatement.

SUMMARY: As provided for under the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received a petition for reinstatement of competitive oil and gas leases OHES058186, OHES058187, OHES058188, OHES058191, OHES058198, OHES058199, OHES058200, OHES058203, OHES058204, OHES058205, and OHES058213 from Eclipse Resources I, LP for land in Monroe County, Ohio. The lessee filed the petition on time, along with all rentals due since the leases terminated under the law. No leases affecting these lands were issued before the petition was filed. The BLM proposes to reinstate the leases.

FOR FURTHER INFORMATION CONTACT: Kathy Gunderman, Branch Chief for Fluid Minerals Adjudication, Bureau of Land Management, Eastern States State Office, 20 M Street SE, Suite 950, Washington, DC 20003; phone 202–912–7721; email *mgunderman@blm.gov.*

Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Kathy Gunderman 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. A reply will be sent during normal business hours.

SUPPLEMENTARY INFORMATION: The lessee agreed to the amended lease terms for rentals and royalties at rates of $10 per acre, or fraction thereof, per year and 16⅔ percent, respectively. The lessee has paid the required $500 administrative fee and the $159 cost of publishing this notice for each lease. The lessee met the requirements for reinstatement of the leases per Sec. 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM proposes to reinstate the leases effective February 1, 2018, under the original

terms and conditions of the leases, and the increased rental and royalty rates cited above.

Authority: 30 U.S.C. 188 (e)(4) and 43 CFR 3108.2–3(b)(2)(v).

Mitchell Leverette,

Acting State Director, Eastern States.

[FR Doc. 2018–20504 Filed 9–19–18; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY920000.L51040000.FI0000. 18XL5017AR]

Notice of Proposed Reinstatement of Terminated Oil and Gas Leases in Wyoming (Southland 17)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: As provided for under the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received petitions for reinstatement of competitive oil and gas leases WYW–177798, WYW–183048, WYW–183798, WYW- 183807, WYW–183830, WYW–185283, WYW–185588, WYW–185589, WYW–185591, WYW–185593, WYW–185594, WYW–185595, WYW–185596, WYW–185597, WYW–185598, WYW–185599, and WYW–185601 from Southland Royalty Company LLC for land in Carbon and Sweetwater Counties, Wyoming. The lessee filed the petitions on time, along with all rentals due since the leases terminated under the law. No new leases affecting these lands were issued before the petitions were filed. The BLM proposes to reinstate the leases.

FOR FURTHER INFORMATION CONTACT: Chris Hite, Branch Chief for Fluid Minerals Adjudication, Bureau of Land Management, Wyoming State Office, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming, 82003; phone 307–775–6176; email *chite@blm.gov.*

Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Hite 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. A reply will be sent during normal business hours.

SUPPLEMENTARY INFORMATION: The lessee agreed to the amended lease terms for rentals and royalties at rates of $10 per acre, or fraction thereof, per year and 16 ⅔ percent, respectively. The lessee has paid the required $500 administrative fee and the $159 cost of publishing this notice. The lessee agreed to additional lease stipulations on lease WYW–177798 to protect nesting raptors, Greater Sage-Grouse habitat, amphibian and reptile species habitat, and to protect the historic and visual values of the Lincoln Highway/Union Pacific Railroad Grade historic property. The lessee agreed to additional lease stipulations on leases WYW–183048, WYW–183807, and WYW–185588 to protect Greater Sage-Grouse habitat. The lessee agreed to additional lease stipulations on lease WYW–183830 to protect raptor nesting habitat. The lessee agreed to the removal of a lease stipulation to protect Greater Sage-Grouse habitat on lease WYW185283 because the lease is no longer within 2 miles of a lek managed as occupied. No additional stipulations were added to the other leases.

The lessee met the requirements for reinstatement of the leases per Sec. 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM proposes to reinstate each of the leases effective on the date of termination, under amended terms and conditions including the increased rental and royalty rates cited above.

Authority: 30 U.S.C. 188(e)(4) and 43 CFR 3108.2–3(b)(2)(v).

Chris Hite,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. 2018–20501 Filed 9–19–18; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1396 (Final)]

Forged Steel Fittings From Taiwan

Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of forged steel fittings from Taiwan that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2]

Background

The Commission instituted this investigation effective October 5, 2017, following receipt of a petition filed with the Commission and Commerce by Bonney Forge Corporation, Mount Union, Pennsylvania, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, Pittsburgh, Pennsylvania. The Commission established a general schedule for the final phase of its investigations on forged steel fittings from China, India, and Taiwan [3] following notifications of preliminary determinations by Commerce that imports of forged steel fittings from China, Italy, and Taiwan were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)).[4] Notice of the scheduling of the final phase of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 4, 2018, (83 FR 25715, June 4, 2018). The hearing was held in Washington, DC, on August 2, 2018, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made this determination pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determination in this investigation on September 14, 2018. The views of the Commission are contained in USITC Publication 4823 (September 2018), entitled *Forged Steel Fittings from Taiwan: Investigation No. 731–TA–1396 (Final).*

By order of the Commission.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] *Forged Steel Fittings From Taiwan: Final Determination of Sales at Less Than Fair Value,* 83 FR 36519, July 30, 2018.

[3] *Forged Steel Fittings From China, India, and Taiwan: Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations,* 83 FR 25715, June 4, 2018.

[4] *Forged Steel Fittings From the People's Republic of China: Affirmative Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 83 FR 22948, May 17, 2018; *Forged Steel Fittings From Italy: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures,* 83 FR 22954, May 17, 2018; and *Forged Steel Fittings From Taiwan: Affirmative Preliminary Determination of Sales at Less Than Fair Value,* 83 FR 22957, May 17, 2018; *see also Forged Steel Fittings From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Duty Determination,* 83 FR 11170, March 14, 2018.

Issued: September 14, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–20441 Filed 9–19–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–944 (Enforcement Proceeding)]

Certain Network Devices, Related Software and Components Thereof (I): Commission Decision To Terminate the Enforcement Proceeding Based on Settlement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to grant the private parties' joint motion to terminate the enforcement proceeding based on settlement. The enforcement proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the underlying investigation on January 27, 2015, based on a complaint filed on behalf of Cisco Systems, Inc. (''Cisco'') of San Jose, California. 80 *FR* 4314–15 (Jan. 27, 2015). The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain network devices, related software and components thereof by reason of infringement of certain claims of U.S. Patent No. 7,162,537 (''the '537 patent''); U.S. Patent No. 8,356,296 (''the '296 patent''); U.S. Patent No. 7,290,164 (''the '164 patent''); U.S. Patent No. 7,340,597 (''the '597 patent''); U.S. Patent No. 6,741,592 (''the '592 patent''); and U.S. Patent No. 7,200,145 (''the '145 patent''), and alleges that an industry in the United States exists as required by subsection (a)(2) of section 337. The '296 patent was withdrawn from the investigation. The notice of investigation named Arista Networks, Inc. (''Arista'') of Santa Clara, California as the respondent. A Commission investigative attorney participated in the investigation.

On June 23, 2016, the Commission found that a Section 337 violation had occurred as to the '537, '592, and '145 patents and therefore issued a limited exclusion order and a cease and desist order (''CDO'') against Arista. 81 *FR* 42375–76 (June 29, 2016).

On August 26, 2016, Cisco filed an enforcement complaint alleging that Arista had violated the June 23, 2016 CDO by reason of infringement of the '537 patent. The Commission instituted this enforcement proceeding on October 4, 2016, based on Cisco's complaint. 81 *FR* 68455 (Oct. 4, 2016).

On August 24, 2018, Cisco and Arista filed a joint motion to terminate the enforcement proceeding based on settlement. The motion includes both confidential and public versions of a binding term sheet, and the parties represent that there are no other agreements, written or oral, express or implied between them concerning the subject matter of the proceeding. The parties also contend that the termination of the investigation would not adversely affect the public interest.

The Commission has determined to grant the joint motion. The Commission finds that the private parties have complied with the Commission's Rules, and that termination of the enforcement proceeding would not adversely affect the public interest. The proceeding is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: September 17, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–20473 Filed 9–19–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain LTE- and 3G-Compliant Cellular Communications Devices, DN 3342;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of INVT SPE LLC on September 14, 2018. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain LTE- and 3G-compliant cellular communications devices. The complaint names as respondents: Apple Inc. of Cupertino, CA; HTC Corporation of China; HTC America, Inc. of Seattle, Washington;

ZTE Corporation of China; and ZTE (USA) Inc. of Richardson, TX. The complainant requests that the Commission issue a limited exclusion order, cease and desist order or orders, and impose a bond during the 60-day review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues should be filed no later than by close of business nine calendar days after the date of publication of this notice in the **Federal Register**. Complainant may file a reply to any written submission no later than the date on which complainant's reply would be due under § 210.8(c)(2) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(c)(2)).

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3342'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electonic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: September 14, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–20429 Filed 9–19–18; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on September 10, 2018, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Media Workflow Association, Inc. has 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, DHD Audio GmbH, Leipzig, GERMANY; and Philip Soares (individual member), Bellevue, WA, have been added as parties to this venture.

Also, Univision, Teaneck, NJ; SuperSport, Johannesburg, SOUTH AFRICA; Xytech Systems Corporation, Mission Hills, CA; Iain Collins (individual member), London, UNITED KINGDOM; and Keith Ian Graham (individual member), San Jose, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. 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 June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on June 22, 2018. A notice was published in the **Federal**

Register pursuant to Section 6(b) of the Act on July 18, 2018 (83 FR 33949).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2018–20497 Filed 9–19–18; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on September 4, 2018, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. (''PXI Systems'') has 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, Power Value Technologies Co., LTD, Shanghai, PEOPLE'S REPUBLIC OF CHINA, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems 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 March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on June 14, 2018. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 9, 2018 (83 FR 31774).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2018–20499 Filed 9–19–18; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Data Collections From Industry-Recognized Apprenticeship Program Accreditors

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA), is soliciting comments concerning proposed authority to conduct the voluntary information collection request (ICR) titled, ''Industry-Recognized Apprenticeship Programs Accrediting Entity Information.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by November 19, 2018.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ETA–2018–0001 or via postal mail, commercial delivery, or hand delivery. A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from *http://www.regulations.gov* or by contacting Mark Judge by telephone at 202–693–3470 (this is not a toll-free number), or by email at *IRAP.PRA@dol.gov.* Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Apprenticeship, Room C–5321, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *IRAP.PRA@dol.gov.*

Comments submitted in response to this comment request will become a matter of public record and will be summarized and included in the request for Office of Management and Budget (OMB) approval of the information collection request. In addition, comments, regardless of the delivery method, will be posted without change on the *http://www.regulations.gov* website; consequently, the Department recommends comments not include personal information such as social security number, personal address, telephone number, email address, or confidential business information that they do not want made public. It is the responsibility of the commenter to determine what to include in the public record.

FOR FURTHER INFORMATION CONTACT: Mark Judge by telephone at 202–693–3470 (this is not a toll-free number) or by email at *IRAP.PRA@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of its continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to OMB for final approval. This program helps to ensure 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 can be properly assessed.

ETA has requested that OMB approve an Information Collection Request pursuant to the Paperwork Reduction Act. If approved, this request will enable ETA to collect essential data under Training and Employment Notice (TEN) No. 3–18 concerning the operational characteristics of certain industry-recognized apprenticeship programs that are being established under the statutory authority of the Act (located at 29 U.S.C. 50).[1]

On June 15, 2017, President Trump issued Executive Order 13801, entitled ''Expanding Apprenticeships in America,'' which directed the Secretary of Labor (in consultation with the Secretaries of Education and Commerce)

[1] Please note that the projected duties of program ''certifiers'' (as referenced in TEN 3–18) in assessing the quality and rigor of industry-recognized apprenticeship programs are the same job functions traditionally performed by accreditation bodies. Accreditation is a statement from an accreditation body—an independent organization that oversees the development of voluntary consensus standards—declaring that another entity offering credentials, education, and/or training within a program (such as an industry-recognized apprenticeship program) has met specified certification standards. Additional information on accreditation bodies can be found at the website of the American National Standards Institute: *https://www.standardsportal.org/usa_en/resources/USaccreditation_bodies.aspx*. The Department intends to elaborate further upon these accreditation duties in amending 29 CFR part 29.

to consider ''proposing regulations, consistent with applicable law, including 29 U.S.C. 50, that promote the development of apprenticeship programs.'' Under section 4(a) of the Executive Order, these accreditors may include trade and industry groups, companies, non-profit organizations, unions, and joint labor-management organizations. Section 4(a) also directs the Department to determine how qualified accreditors may provide recognition to ''industry-recognized apprenticeship programs,'' and to ''establish guidelines or requirements that qualified [accreditors] should or must follow to ensure that [the industry-recognized] apprenticeship programs they recognize meet quality standards.''

The Secretary has determined to move forward with the development of the industry-recognized apprenticeship programs contemplated by the foregoing provisions of the Executive Order. To accomplish this goal, the Department issued an interim informational and guidance document (TEN No., 3–18) on July 27, 2018 titled ''Creating Industry-Recognized Apprenticeship Programs to Expand Opportunity in America.'' According to the TEN, these new industry-recognized apprenticeship programs will be reviewed and recognized by qualified accrediting entities; the accrediting entities, in turn, may request a determination from the Department concerning their qualifications to act as a accreditor. The Department intends to promulgate a regulation amending 29 CFR part 29; this regulation would, among other things, establish guidelines or requirements that qualified entities must follow to ensure that the industry-recognized programs they accredit meet quality standards.

The TEN provides interim information and guidance to accreditors on the process for obtaining a determination from the Department on whether that entity's standards meet the criteria outlined in TEN No. 3–18. To obtain a favorable determination from the Department, the accrediting entity should, among other things, demonstrate that it has received broad sector-wide input and consensus in the setting of industry-wide quality standards. The accrediting entity should also demonstrate that their program accreditation process ensures that the industry programs will operate in a manner consistent with DOL-identified hallmarks of high-quality apprenticeship programs. To collect the information necessary for the Department to determine whether the entity accrediting these industry-recognized apprenticeship programs has satisfied the foregoing criteria, the Department proposes the development of a form titled ''Industry-Recognized Apprenticeship Programs Accrediting Entity Information,'' intended for completion by the accrediting entity, that will enable the Department to determine whether that entity's standards meet the criteria outlined in the TEN. An electronic version of this information collection form will be posted on the Department's website, and will be capable of being completed and submitted online.

Under the National Apprenticeship Act of 1937, the Secretary of Labor is charged with the establishment of labor standards designed to safeguard the welfare of apprentices and promote apprenticeship opportunity. Pursuant to this statutory authority, and in furtherance of the policy objectives stated in Executive Order 13801, the Secretary has determined that the immediate establishment of industry-recognized apprenticeship programs is a matter of vital national interest. 44 U.S.C. 3506(c)(2)(A) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section of this notice. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention 1205–0NEW.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments. DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Type of Review: New.

Title of Collection: Data Collections from Industry-Recognized Programs Accreditors.

Form: Industry-Recognized Apprenticeship Programs Accrediting Entity Information.

OMB Control Number: 1205–0NEW.

Affected Public: Individuals/households, state/local/tribal governments, Federal government, private sector (businesses or other for-profits, and, not-for-profit institutions).

Estimated Total Annual Respondents: 308.

Estimated Number of Respondents: 308.

Frequency: Generally, once every five years.

Total Estimated Annual Responses: 308.

Estimated Average Time per Response: 82 minutes.

Estimated Total Annual Burden Hours: 6,980.

Total Estimated Annual Other Cost Burden: $0.

Rosemary Lahasky,

Deputy Assistant Secretary for the Employment and Training Administration.

[FR Doc. 2018–20436 Filed 9–19–18; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

[Agency Docket Number DOL–2018–0005]

Notice of Publication of 2018 Update to the Department of Labor's List of Goods Produced by Child Labor or Forced Labor

AGENCY: Office of the Secretary, Bureau of International Labor Affairs, Department of Labor.

ACTION: Announcement of public availability of updated list of goods.

SUMMARY: This notice announces the publication of an updated list of goods—along with countries of origin—that the Bureau of International Labor Affairs (ILAB) has reason to believe are produced by child labor or forced labor in violation of international standards (TVPRA List). ILAB is required to develop and make available to the public the TVPRA List pursuant to the Trafficking Victims Protection Reauthorization Act (TVPRA) of 2005, as amended.

FOR FURTHER INFORMATION CONTACT: Rachel Rigby, Office of Child Labor, Forced Labor, and Human Trafficking, Bureau of International Labor Affairs, U.S. Department of Labor, at (202) 693–4843 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Bureau of International Labor Affairs (ILAB) announces the publication of the eighth edition of the *List of Goods Produced by Child Labor or Forced Labor* (TVPRA List), pursuant to the Trafficking Victims Protection Reauthorization Act (TVPRA) of 2005, as amended. ILAB published the initial TVPRA List on September 10, 2009, and has since published seven updated editions. The 2018 edition adds 10 new goods (amber, bovines, cabbages, carrots, cereal grains, lettuce, mica, peppers, sheep, and sweet potatoes) from particular countries and one new country (Eswatini) to the TVPRA List. This edition also features the removal from the TVPRA List of physic nuts from Burma produced by forced labor, sugarcane from Panama produced by child labor, and cotton from both Paraguay and Uzbekistan produced by child labor.

Section 105(b) of the TVPRA mandates that ILAB develop and publish a list of goods from countries that ILAB ''has reason to believe are produced by forced labor or child labor in violation of international standards.'' 22 U.S.C. 7112(b)(2). ILAB's Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) carries out this mandate. The primary purposes of the TVPRA List are to raise public awareness about the incidence of child labor and forced labor in the production of goods in the countries listed and to promote efforts to eliminate such practices. A full report, including the updated TVPRA List and a discussion of the TVPRA List's methodology, as well as Frequently Asked Questions and a bibliography of sources, are available on the Department of Labor website at: *http://www.dol.gov/ilab/reports/child-labor/list-of-goods/.*

Authority: 22 U.S.C. 7112(b)(2)(C).

Signed at Washington, DC, this 13th day of September 2018.

Martha E. Newton,

Deputy Undersecretary for International Affairs.

[FR Doc. 2018–20391 Filed 9–19–18; 8:45 am]

BILLING CODE 4510–28–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (18–070)]

NASA Astrophysics Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Astrophysics Advisory Committee. This Committee reports to the Director, Astrophysics Division, Science Mission Directorate, NASA Headquarters. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Monday, October 22, 2018, 11:00 a.m.–5:00 p.m.; and Tuesday, October 23, 2018, 11:00 a.m.–5:00 p.m., Eastern Time.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, fax (202) 358–2779, or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number 1–888–324–2912 or toll number 1–312–470–7002, passcode 7682264, to participate in this meeting by telephone on both days. The WebEx link is *https://nasa.webex.com/*; the meeting number on October 22 is 991 683 794, password is APAC1018#; and the meeting number on October 23 is 998 343 087, password is APAC1018#.

The agenda for the meeting includes the following topics:

- Astrophysics Division Update
- Updates on Specific Astrophysics Missions
- Reports from the Program Analysis Groups

The agenda will be posted on the Astrophysics Advisory Committee web page: *https://science.nasa.gov/researchers/nac/science-advisory-committees/apac.*

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2018–20426 Filed 9–19–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by October 22, 2018. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address, 703–292–8030, or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2019–007

1. Applicant

Natasja van Gestel, Texas Tech University, Biological Sciences Department, 2901 Main Street, Lubbock, TX 79409.

Activity for Which Permit Is Requested: Enter Antarctic Specially Protected Area, collect soil and vegetation samples. The applicant proposes to enter Antarctic Specially Protected Area (ASPA) 113, Litchfield Island, Arthur Harbor, to study Antarctic soils, microbial communities, and vegetation. The studies would involve short-term, temporary installation of chambers around study plots; temporary installations of data loggers, sensors, and gauges; minimal soil sample collection; and collection of minimal vegetation samples. The applicant would collect 5 plants each of the species *Deschampsia antarctica* and *Colobanthus quitensis* and up to 20 small samples of various moss species. Moss samples would be collected near Palmer Station preferentially, if species are available there. All samples would be taken to the home institution for analysis and, ultimately, herbarium curation.

Location: ASPA 113, Litchfield Island, Arthur Harbor; Anvers Island, Palmer Station area.

Dates of Permitted Activities: December 5, 2018–April 10, 2019.

Permit Application: 2019–008

2. Applicant

Caitlin Saks, WGBH, 1 Guest Street, Boston, MA 02135.

Activity for Which Permit Is Requested: Enter Antarctic Specially Protected Areas (ASPA). The applicant would enter ASPA 121, Cape Royds, Ross Island; ASPA 155, Cape Evans, Ross Island; ASPA 157, Backdoor Bay, Cape Royds, Ross Island; ASPA 158, Hut Point, Ross Island; ASPA 172, Lower Taylor Glacier and Blood Falls, Taylor Valley to film scientific research being conducted, historically significant locations, and the natural environment. The resulting film and photography would be used to create a series of media products including a two-hour documentary. The applicant proposes to employ a video-camera and tripod, possibly a light stand (inside historic huts), a 360 degree virtual reality camera, and, where feasible and allowable, a small, remotely piloted aircraft system with a camera payload. The applicant would enter the historic huts with a trained guide and would abide by the management plans of all ASPAs visited. The results of this work are expected to be useful for outreach and education about Antarctica and the scientific research conducted there.

Location: ASPA 121, Cape Royds, Ross Island; ASPA 155, Cape Evans, Ross Island; ASPA 157, Backdoor Bay, Cape Royds, Ross Island; ASPA 158, Hut Point, Ross Island; ASPA 172, Lower Taylor Glacier and Blood Falls, Taylor Valley; McMurdo Station area; McMurdo Dry Valleys.

Dates of Permitted Activities: October 22–November 19, 2018.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2018–20470 Filed 9–19–18; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for International Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Proposal Review Panel for Office of International Science and Engineering—PIRE: Translating Cognitive and Brain Science in the Laboratory and Field to Language Learning Environments—Reverse Site Visit (#10749).

Date and Time: October 25, 2018; 8:00 a.m.–5:00 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

Type of Meeting: Part-Open.

Contact Person: Cassandra Dudka, PIRE Program Manager, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone 703/292–7250.

Purpose of Meeting: NSF reverse site visit to conduct a review during year 3 of the five-year award period. To conduct an in-depth evaluation of performance, to assess progress towards goals, and to provide recommendations.

Agenda: See attached.

Reason for Closing: Topics to be discussed and evaluated during closed portions of the site review will include information of a proprietary or confidential nature, including technical information; and information on personnel. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: September 17, 2018.

Crystal Robinson,

Committee Management Officer.

National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314

Partnerships for International Research and Education (PIRE)

Reverse Site Visit Agenda—NSF Room C3010

Thursday, October 25, 2018

8:00 a.m. Panelists arrive. Coffee/light refreshments available.
8:15 a.m.–8:45 a.m. Panel Orientation—(CLOSED)
PIRE Rationale and Goals, Charge to Panel
8:45 a.m. PIs arrive. Introductions. (OPEN)
9:00 a.m.–11:30 a.m. PIRE Project Presentation should cover the following: (OPEN)
Research
Integrating Research & Education
Students (*e.g.* involvement in project, recruitment, diversity)
Project Management and Communication
Evaluation & Assessment
Institutional Support
International Partnerships
11:30 a.m.–12:30 p.m. Questions and Answers
12:30 p.m.—2:00 p.m. Working Lunch—Panel Discussion—(CLOSED)
2:00 p.m.–2:30 p.m. Initial Feedback to Project Team (CLOSED)
2:30 p.m. PIRE PI and presenters are dismissed
2:30 p.m.–4:30 p.m. Panel meets for Reverse Site Visit Report Preparation—(CLOSED)
4:30 p.m.–4:45 p.m. Report presented to and discussion held with NSF staff—(CLOSED)
5:00 p.m. End of Reverse Site Visit

[FR Doc. 2018–20454 Filed 9–19–18; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Education and Human Resources; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Education and Human Resources (EHR) (#1119).

Date and Time: October 18, 2018; 8:00 a.m.–5:00 p.m.

October 19, 2018; 8:00 a.m.–2:00 p.m.

Place: National Science Foundation, 2415 Eisenhower Avenue, Room E2020, Alexandria, VA 22314.

To attend the meeting in person, all visitors must contact the Directorate for Education and Human Resources at least 48 hours prior to the meeting to arrange for a visitor's badge. All visitors

must access NSF via the Visitor Center entry adjacent to the south building entrance on Eisenhower Avenue on the day of the meeting to receive a visitor's badge. It is suggested that visitors allow time to pass through security screening.

Type of Meeting: Open.

Contact Person: Keaven M. Stevenson, National Science Foundation, 2415 Eisenhower Avenue, Room C11001, Alexandria, VA 22314; (703) 292–8600/ *kstevens@nsf.gov.*

Summary of Minutes: Minutes and meeting materials will be available on the EHR Advisory Committee website at *http://www.nsf.gov/ehr/advisory.jsp* or can be obtained from Dr. Ellen McCallie, National Science Foundation, 2415 Eisenhower Ave., Room C11233, Alexandria, VA 22314; (703) 292–8600; *emccalli@nsf.gov.*

Purpose of Meeting: To provide advice with respect to the Foundation's science, technology, engineering, and mathematics (STEM) education and human resources programming.

Agenda

Thursday, October 18, 2018, 8:00 a.m.–5:00 p.m.

Remarks by the EHR AC Committee Chair and the EHR Assistant Director for Education and Human Resources (EHR).

Public Private Partnerships.

STEM Education of the Future.

Mid-scale Research Infrastructure.

Broadening Participation.

Discussion with France Córdova, NSF Director and F. Fleming Crim, Chief Operating Officer.

Friday, October 19, 2018, 8:00 a.m.–2:00 p.m.

Day 1 Recap.

Quick briefings.

Update on EHR Programs.

Update on Subcommittees Reflections from the EHR AD.

Committee Business.

Advisory Committee Recommendations.

Final agenda can be located on the EHR AC website: *https://www.nsf.gov/ehr/advisory.jsp.*

Dated: September 17, 2018.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2018–20453 Filed 9–19–18; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0145]

Proposed Revisions to Branch Technical Position 5–3: Fracture Toughness Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan—draft section revision; reopening of comment period.

SUMMARY: On July 13, 2018, the U.S. Nuclear Regulatory Commission (NRC) published a request for public comment on draft NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' Branch Technical Position (BTP) 5–3, ''Fracture Toughness Requirements.'' The public comment period was originally scheduled to close on September 11, 2018. The NRC has decided to reopen the public comment period on this document for 30 days to allow more time for members of the public to review additional revisions that the NRC made to BTP 5–3 since the draft was issued on July 13, 2018, and to assemble and submit their comments.

DATES: The comment period for the document published on July 13, 2018 (83 FR 32690) has been reopened. Comments must be filed no later than October 22, 2018. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0145. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* May Ma, Office of Administration, Mail Stop: TWFN 7 A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Mark D. Notich, Office of New Reactors, telephone: 301–415–3053; email: *Mark.Notich@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0145 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0145.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2018–0145 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Further Information

On July 13, 2018 (83 FR 32690), the NRC published a request for public

comment on draft NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' BTP 5–3, ''Fracture Toughness Requirements,'' (ADAMS Accession No. ML18081A184). This section has been developed to assist NRC staff in reviewing applications submitted per the requirements under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR).

The public comment period was originally closed on September 11, 2018. The NRC has included additional revisions to the text of BTP 5–3 since the section was issued for comment. Accordingly, the NRC has decided to reopen the public comment period on this document to allow more time for members of the public to assemble and submit their comments. The revised text for BTP 5–3 can be found in ML18254A090. The redline/strikeout comparing the current version of BTP 5–3 and the revised version can be found in ML18257A032.

Dated at Rockville, Maryland, this 17th day of September 2018.

For the Nuclear Regulatory Commission.

Jennivine K. Rankin,

Acting Branch Chief, Licensing Branch 3, Division of Licensing, Siting, and Environmental Analysis, Office of New Reactors.

[FR Doc. 2018–20451 Filed 9–19–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0206]

Protection Against Malevolent Use of Vehicles at Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 5.68, ''Protection against Malevolent use of Vehicles at Nuclear Power Plants,'' dated August 1994. This document is being withdrawn because it is outdated and has been superseded by other NRC guidance. Therefore, it no longer provides methods that the NRC staff finds acceptable to protect against the malevolent use of vehicles as a means to gain unauthorized access to protected areas and vital areas and to ensure that these vehicles are operated only by authorized persons with a legitimate need for access.

DATES: The effective date of the withdrawal of RG 5.68 is September 20, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0206 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0206. Address questions about NRC dockets in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced. The basis for withdrawal of RG 5.68 is available in ADAMS under Accession No. ML18187A345.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Bernard Stapleton, telephone: 301–287–3532, email: *Bernard.Stapleton@nrc.gov,* or Mekonen Bayssie, telephone: 301–415–1699, email: *Mekonen.Bayssie@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC is withdrawing RG 5.68, ''Protection against Malevolent use of Vehicles at Nuclear Power Plants,'' because the guidance contained in the document is outdated, has been superseded by new guidance, and therefore is no longer acceptable to meet NRC regulatory requirements. In particular, on March 27, 2009, the NRC issued a revised rule that enhanced the security requirements pertaining to nuclear power plants to incorporate requirements that were issued through Commission orders as a result of the September 11, 2001, terrorist attacks (74 FR 13925). In addition, the rulemaking added several new requirements consistent with insights gained from implementation of the orders, review of site security plans, implementation of the enhanced baseline inspection program, and NRC evaluation of force-on-force exercises. Since RG 5.68 was published in August 1994, it does not account for the updated requirements of 10 CFR part 73. As a result, the guidance in RG 5.68 is outdated. In addition, the NRC is withdrawing RG 5.68 because it has been superseded by updated guidance that can be found in other regulatory documents. These documents provide licensees with acceptable approaches to address various issues, including vehicle access controls, use of explosives, target set identification and the appropriate use of vehicles.

II. Further Information

The withdrawal of RG 5.68 does not alter any prior or existing NRC licensing approval or the acceptability of licensee commitments made in accordance with the withdrawn guidance. Although RG 5.68 is withdrawn, current licensees referencing this RG may continue to do so, and withdrawal does not affect any existing licenses or agreements. However, by withdrawing RG 5.68, the NRC will no longer approve use of the guidance in future requests or applications for NRC licensing actions.

Dated at Rockville, Maryland, this 17th day of September, 2018.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2018–20476 Filed 9–19–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–247 and 50–286; NRC–2008–0672]

Entergy Nuclear Operations, Inc.: Indian Point Nuclear Generating Unit Nos. 2 and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal and record of decision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued renewed Facility Operating License Nos. DPR–26

and DPR–64 to Entergy Nuclear Operations, Inc. (Entergy or licensee), for Indian Point Nuclear Generating Unit Nos. 2 (IP2) and 3 (IP3). Renewed Facility Operating License Nos. DPR–26 and DPR–64 authorize Entergy to operate IP2 and IP3 at reactor core power levels not in excess of 3,216 megawatts thermal for each unit, in accordance with the provisions of the IP2 and IP3 renewed licenses and technical specifications. In addition, the NRC has prepared a Record of Decision (ROD) that supports the NRC's decision to issue renewed Facility Operating License Nos. DPR–26 and DPR–64.

DATES: The NRC issued the Renewed Facility Operating License Nos. DPR–26 and DPR–64 on September 17, 2018.

ADDRESSES: Please refer to Docket ID NRC–2008–0672 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0672. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William Burton, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–6332, email: *William.Burton@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

Notice is hereby given that the NRC has issued Renewed Facility Operating License Nos. DPR–26 and DPR–64 to Entergy Nuclear Operations, Inc. (Entergy or licensee), for the Indian Point Nuclear Generating Unit Nos. 2 (IP2) and 3 (IP3). IP2 and IP3 are pressurized-water reactors located in Buchanan, NY (24 miles north of New York City, NY). Renewed Facility Operating License Nos. DPR–26 and DPR–64 authorize the licensee to operate IP2 and IP3 at reactor core power levels not in excess of 3,216 megawatts thermal for each unit, in accordance with the provisions of the IP2 and IP3 renewed licenses and technical specifications. The renewed licenses authorize operation of IP2 and IP3 until April 30, 2024 and April 30, 2025, respectively. The NRC's record of decision (ROD) that supports the NRC's decision to issue Renewed Facility Operating License Nos. DPR–26 and DPR–64 is available in ADAMS under Accession No. ML18212A032.

The NRC has concluded that the application for the renewed licenses, ''Indian Point Energy Center License Renewal Application,'' dated April 23, 2007 (ADAMS Accession No. ML071210512), as amended, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the NRC's regulations. As required by the Act and the NRC's regulations set forth in title 10 of the *Code of Federal Regulations* (10 CFR), the NRC has made appropriate findings, which are set forth in the renewed licenses. No adjudicatory matters are pending before the Commission or the Atomic Safety and Licensing Board regarding the IP2 and IP3 license renewal application.

The NRC staff published its final supplemental environmental impact statement (FSEIS) in five volumes of NUREG–1437, Supplement 38, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Indian Point Nuclear Generating Unit Nos. 2 and 3 (NUREG–1437, Supplement 38) Final Report.'' For Volumes 1 through 3, dated December 3, 2010, see ADAMS Package Accession No. ML103270072; for Volume 4, dated June 30, 2013 (FSEIS Supplement 1), see ADAMS Accession No. ML13162A616; and for Volume 5, dated April 30, 2018 (FSEIS Supplement 2), see ADAMS Accession No. ML18107A759. As discussed in the ROD, FSEIS, and FSEIS supplements, the NRC has considered the reasonably foreseeable impacts of IP2 and IP3 license renewal as well as a range of reasonable alternatives to license renewal that included natural gas combined-cycle (NGCC); purchased electric power; conservation; combination alternative 1 (license renewal of either IP2 or IP3 along with wind power, hydropower, biomass fuels, landfill-gas fuels, and conservation); combination alternative 2 (fossil-fired power (combined-cycle) with wind power, biomass fuels, hydropower, landfill-gas fuels, and conservation); the no-action alternative; and operation of IP2 and IP3 using cooling towers. The FSEIS and FSEIS supplements document the environmental review, including the determination that the adverse environmental impacts of license renewal for IP2 and IP3 are not so great that preserving the option of license renewal for energy planning decisionmakers would be unreasonable.

The NRC staff documented the results of its safety review in its ''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3,'' issued August 11, 2009 (ADAMS Accession No. ML092240268). On November 30, 2009, the NRC staff published its final report in two volumes as NUREG–1930, ''Safety Evaluation Report Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (for Volume 1, see ADAMS Accession No. ML093170451 and for Volume 2 see ADAMS Accession No. ML093170671). On August 31, 2011, the NRC staff issued Supplement 1 to NUREG–1930 (ADAMS Accession No. ML11242A215). Supplement 1 documents the NRC staff's review of supplemental information provided by the applicant since the issuance of NUREG–1930, including annual updates required by 10 CFR 54.21(b), and updated information and commitments in response to NRC staff requests for additional information. On July 31, 2015, the NRC staff issued Supplement 2 to NUREG–1930 (ADAMS Accession No. ML15188A383). Supplement 2 documents the NRC staff's review of supplemental information provided by the applicant since the issuance of Supplement 1, including information committed to by Entergy as documented in Commitment No. 30 (pertaining to reactor vessel internals), annual updates required by 10 CFR 54.21(b), updated information and commitments, as well as information provided in response to NRC staff requests for additional information. On August 1, 2018, the NRC staff issued Supplement 3 to NUREG–1930 (ADAMS Accession No.

ML18200A333). Supplement 3 documents the NRC staff's review of supplemental information provided by the applicant since the issuance of Supplement 2, including annual updates required by 10 CFR 54.21(b), updated information to address new or updated interim staff guidance, and recent operating experience.

II. Conclusion

The NRC has determined that the application for the Indian Point Nuclear Generating Unit Nos. 2 and 3 renewed licenses, ''Indian Point Energy Center License Renewal Application,'' dated April 23, 2007, as amended, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the NRC's regulations. As required by the Act and the NRC's regulations in 10 CFR, the NRC has made appropriate findings, which are set forth in the renewed licenses and the ROD. No adjudicatory matters are pending before the Commission or the Atomic Safety and Licensing Board regarding the IP2 and IP3 license renewal application.

Accordingly, the NRC has issued Renewed Facility Operating License Nos. DPR–26 and DPR–64, authorizing operation of IP2 and IP3 until April 30, 2024 and April 30, 2025, respectively.

III. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS accession No.
Indian Point Energy Center License Renewal Application,'' dated April 23, 2007	ML071210512.
NUREG-1437, Supplement 38, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Indian Point Nuclear Generating Unit Nos. 2 and 3 (NUREG–1437, Supplement 38) Final Report.'' (Volumes 1–3, December 3, 2010).	ML103270072.
NUREG-1437, Supplement 38, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Indian Point Nuclear Generating Unit Nos. 2 and 3 (NUREG–1437, Supplement 38) Final Report.'' (Volume 4, June 30, 2013).	ML13162A616.
NUREG-1437, Supplement 38, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Indian Point Nuclear Generating Unit Nos. 2 and 3 (NUREG–1437, Supplement 38) Final Report.'' (Volume 5, April 30, 2018).	ML18107A759.
''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (August 11, 2009).	ML092240268.
NUREG–1930, ''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (Volume 1 November 30, 2009).	ML093170451.
NUREG–1930 ''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (Volume 2 November 30, 2009).	ML093170671.
NUREG–1930 ''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (August 31, 2011).	ML11242A215.
NUREG–1930 ''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (July 31, 2015).	ML15188A383.
NUREG–1930 ''Safety Evaluation Report (SER) Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3'' (August 1, 2018).	ML18200A333.
Record of Decision for License Renewal Application For Indian Point Nuclear Generating (September 17, 2018)	ML18212A032.

Dated at Rockville, MD, this 17th day of September 2018.

For the Nuclear Regulatory Commission.

George A. Wilson, Jr.,

Director, Division of Materials and License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–20450 Filed 9–19–18; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2018–216; MC2018–221 and CP2018–307]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 24, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s)

[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).

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).:* CP2018–216; *Filing Title:* Notice of the United States Postal Service of Filing Modification Two to a Global Plus 4 Negotiated Service Agreement; *Filing Acceptance Date:* September 14, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* September 24, 2018.

2. *Docket No(s).:* MC2018–221 and CP2018–307; *Filing Title:* USPS Request to Add Parcel Select Contract 33 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* September 14, 2018; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5*; Public Representative:* Kenneth R. Moeller; *Comments Due:* September 24, 2018.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–20496 Filed 9–19–18; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Sunshine Act Meetings; Temporary Emergency Committee of the Board of Governors

TIME AND DATE: Tuesday, September 11, 2018, at 8:30 a.m. and Wednesday, September 12, 2018, at 8:30 a.m.

PLACE: Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Tuesday, September 11, 2018, at 8:30 a.m.

1. Strategic Items.
2. Executive Session.

Wednesday, September 12, at 8:30 a.m.

1. Strategic Items.
2. Financial Matters.
3. Executive Session.

General Counsel Certification: The General Counsel of the United States Postal Service has certified that these meetings may be closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Acting Secretary.

[FR Doc. 2018–20602 Filed 9–18–18; 4:15 pm]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Select 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 notice required under 39 U.S.C. 3642(d)(1):* September 20, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 14, 2018, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Select Contract 33 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2018–221, CP2018–307.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–20440 Filed 9–19–18; 8:45 am]

BILLING CODE 7710–12–P

PRESIDIO TRUST

Notice of Public Meeting

AGENCY: The Presidio Trust.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Presidio Trust Act, and in accordance with the Presidio Trust's bylaws, notice is hereby given that a public meeting of the Presidio Trust Board of Directors will be held commencing 5:00 p.m. on October 18, 2018, at the Officers' Club, 50 Moraga Avenue, Presidio of San Francisco, California.

The purposes of this meeting are to: Provide the Board Chair's report; provide the Chief Executive Officer's report; hold a National Environmental Policy Act scoping workshop for the Fort Winfield Scott project; and receive public comment on these and other matters pertaining to Trust business.

Individuals requiring special accommodation at this meeting, such as needing a sign language interpreter, should contact Mollie Matull at 415.561.5300 prior to October 9, 2018.

DATES: The meeting will begin at 5:00 p.m. on October 18, 2018.

ADDRESSES: The meeting will be held at the Officers' Club, 50 Moraga Avenue, Presidio of San Francisco.

FOR FURTHER INFORMATION CONTACT: Nancy J. Koch, General Counsel, the Presidio Trust, 103 Montgomery Street, P.O. Box 29052, San Francisco, California 94129–0052, Telephone: 415.561.5300.

Dated: September 13, 2018.

Nancy J. Koch,

General Counsel.

[FR Doc. 2018–20492 Filed 9–19–18; 8:45 am]

BILLING CODE 4310–4R–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84141; File No. SR–C2–2018–020]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Rules Relating to Categories of Registration and Respective Qualification Examinations Required for Trading Permit Holders (''TPHs'') and Associated Persons That Engage in Trading Activities on the Exchange

September 14, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 7, 2018, 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 Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 its rules relating to categories of registration and respective qualification examinations required for Trading Permit Holders (''TPHs'') and associated persons that engage in trading activities on the Exchange.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The SEC recently approved a proposed rule change to restructure the FINRA representative-level qualification examination program.[3] The rule change, which will become effective on October 1, 2018, restructures the examination program into a more efficient format whereby all new representative-level applicants will be required to take a general knowledge examination (the Securities Industry Essentials Examination (''SIE'')) and a tailored, specialized knowledge examination (a revised representative-level qualification examination) for their particular registered role. Individuals are not required to be associated with an Exchange or any other self-regulatory organization (''SRO'') member to be eligible to take the SIE. However, passing the SIE alone will not qualify an individual for registration with the Exchange. To be eligible for registration, an individual must also be associated with a firm, pass an appropriate qualification examination for a representative or principal and satisfy the other requirements relating to the registration process.

The SIE would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. In particular, the SIE will cover four major areas. The first, ''Knowledge of Capital Markets,'' focuses on topics such as types of markets and offerings, broker-dealers and depositories, and economic cycles. The second, ''Understanding Products and Their Risks,'' covers securities products at a high level as well as associated investment risks. The third, ''Understanding Trading, Customer Accounts and Prohibited Activities,'' focuses on accounts, orders, settlement and prohibited activities. The final area, ''Overview of the Regulatory Framework,'' encompasses topics such as SROs, registration requirements and specified conduct rules. It's anticipated that the SIE would include 75 scored questions plus an additional 10 unscored pretest questions. The passing score would be determined through methodologies compliant with testing industry standards used to develop examinations and set passing standards.

The restructured program eliminates duplicative testing of general securities knowledge on the current representative-level qualification examinations by moving such content into the SIE. The SIE will test fundamental securities related knowledge, including knowledge of basic products, the structure and function of the securities industry, the regulatory agencies and their functions and regulated and prohibited practices, whereas the revised representative-level qualification examinations will test knowledge relevant to day-to-day activities, responsibilities and job functions of representatives. The SIE was developed in consultation with a committee of industry representatives and representatives of several other SROs. Each of the current representative-level examinations covers general securities knowledge, with the exception of the Research Analyst (Series 86 and 87) examinations.

The Exchange proposes to require that effective October 1, 2018, new applicants seeking to register in a representative capacity with the Exchange must pass the SIE before their registrations can become effective. The Exchange proposes to make the requirement operative on October 1, 2018 to coincide with the effective date of FINRA's requirement.[4]

The Exchange notes that individuals who are registered as of October 1, 2018 are eligible to maintain their registrations without being subject to any additional requirements. Individuals who had been registered within the past two years prior to October 1, 2018, would also be eligible to maintain those registrations without being subject to any additional requirements, provided they register within two years from the date of their last registration. However, with respect to an individual who is not registered on the effective date of the proposed rule change but was registered within the past two years prior to the effective date of the proposed rule change, the individual's SIE status in the CRD system would be administratively terminated if such individual does not register with the Exchange within four years from the date of the individual's last registration. The Exchange also notes that consistent with Interpretation and Policy .04 of Rule 3.4, the Exchange will consider waivers of the SIE alone or the SIE and the representative or principal-level examination(s) for TPHs who are seeking registration in a representative- or principal-level registration category.[5]

Lastly, the Exchange proposes to adopt Interpretation and Policy .08 of Rule 3.4 to provide individuals who are associated persons of firms and who hold foreign registrations an alternative, more flexible, process to obtain an Exchange representative-level registration.[6] The Exchange believes

[3] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[4] The Exchange notes that the Exchange's affiliate, Cboe Exchange, Inc. (''Cboe Options'') is also submitting a similar rule change to require the SIE for representative-level registrations. In that rule filing, Cboe Options proposes to make clear in Rule 9.3 that persons required to register as a General Securities Representative must also pass the SIE. The Exchange notes that Chapter IX of Cboe Options Rules is incorporated by reference and as such, the proposed requirement will similarly apply to the Exchange.

[5] Pursuant to a Regulatory Services Agreement between FINRA and the Exchange, FINRA provides the Exchange certain exam waiver services in responding to exam waiver requests from Exchange TPHs.

[6] As previously noted, Cboe Options is submitting a similar rule change which includes the proposed language in Rule 3.4.08. Cboe Options also proposes to include such language in a new Interpretation and Policy .02 of Cboe Options Rule 9.3 to make clear that such requirement also applies to representative-level registrations required for persons who do business with the public. Chapter IX of Cboe Options Rules is incorporated by reference and as such, the proposed requirement will similarly apply to the Exchange.

that there is sufficient overlap between the SIE and these foreign qualification requirements to permit them to act as exemptions to the SIE. As such the Exchange proposes to provide that individuals who are in good standing as representatives with the Financial Conduct Authority in the United Kingdom or with a Canadian stock exchange or securities regulator would be exempt from the requirement to pass the SIE, and thus would be required only to pass a specialized knowledge examination to register with the Exchange as a representative. The proposed approach would provide individuals with a United Kingdom or Canadian qualification more flexibility to obtain an Exchange representative-level registration. The Exchange notes that FINRA has adopted a similar rule.[7]

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.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will improve the efficiency of the Exchange's examination requirements, without compromising the qualification standards, by eliminating duplicative testing of general securities knowledge on examinations. FINRA has indicated that the SIE was developed in an effort to adopt an examination that would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. The Exchange also notes that the introduction of the SIE and expansion of the pool of individuals who are eligible to take the SIE, has the potential of enhancing the pool of prospective securities industry professionals by introducing them to securities laws, rules and regulations and appropriate conduct before they join the industry in a registered capacity. Lastly, the Exchange notes adopting the SIE requirement is consistent with the requirement recently adopted by FINRA.[11]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change, which harmonizes its rules with recent rule changes adopted by FINRA and which is being filed in conjunction with similar filings by the other national securities exchanges, will reduce the regulatory burden placed on market participants engaged in trading activities across different markets. The Exchange believes that the harmonization of these registration requirements across the various markets will reduce burdens on competition by removing impediments to participation in the national market system and promoting competition among participants across the multiple national securities exchanges.

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 written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative on October 1, 2018 to coincide with the effective date of FINRA's proposed rule change on which the proposal is based.[14] The waiver of the operative delay would make the Exchange's qualification requirements consistent with those of FINRA. Therefore, the Commission believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposal operative on October 1, 2018.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2018–020 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–C2–2018–020. This file

[7] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *Id.*

[11] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See supra* note 3.

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–C2–2018–020 and should be submitted on or before October 11, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20431 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84123; File No. SR–NYSEArca–2018–43]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Regarding Investments of the First Trust TCW Unconstrained Plus Bond ETF

September 14, 2018.

On July 11, 2018, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify investments of the First Trust TCW Unconstrained Plus Bond ETF, the shares of which are currently listed and traded on the Exchange pursuant to NYSE Arca Rule 8.600–E. The proposed rule change was published for comment in the **Federal Register** on August 1, 2018.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is September 15, 2018. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates October 30, 2018 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2018–43).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20437 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 83720 (July 26, 2018), 83 FR 37560.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84140; File No. SR–CboeEDGA–2018–015]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Relating to Categories of Registration and Respective Qualification Examinations Required for Members That Engage in Trading Activities on the Exchange

September 14, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 7, 2018, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its rules relating to categories of registration and respective qualification examinations required for Members that engage in trading activities on the Exchange.

The text of the proposed rule change is available at the Exchange's website at *www.markets.cboe.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts 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 SEC recently approved a proposed rule change to restructure the FINRA representative-level qualification examination program.[3] The rule change, which will become effective on October 1, 2018, restructures the examination program into a more efficient format whereby all new representative-level applicants will be required to take a general knowledge examination (the Securities Industry Essentials Examination (''SIE'')) and a tailored, specialized knowledge examination (a revised representative-level qualification examination) for their particular registered role. Individuals are not required to be associated with an Exchange or any other self-regulatory organization (''SRO'') member to be eligible to take the SIE. However, passing the SIE alone will not qualify an individual for registration with the Exchange. To be eligible for registration, an individual must also be associated with a firm, pass an appropriate qualification examination for a representative or principal and satisfy the other requirements relating to the registration process.

The SIE would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. In particular, the SIE will cover four major areas. The first, ''Knowledge of Capital Markets,'' focuses on topics such as types of markets and offerings, broker-dealers and depositories, and economic cycles. The second, ''Understanding Products and Their Risks,'' covers securities products at a high level as well as associated investment risks. The third, ''Understanding Trading, Customer Accounts and Prohibited Activities,'' focuses on accounts, orders, settlement and prohibited activities. The final area, ''Overview of the Regulatory Framework,'' encompasses topics such as SROs, registration requirements and specified conduct rules. It's anticipated that the SIE would include 75 scored questions plus an additional 10 unscored pretest questions. The passing score would be determined through methodologies compliant with testing industry standards used to develop examinations and set passing standards.

The restructured program eliminates duplicative testing of general securities knowledge on the current representative-level qualification examinations by moving such content into the SIE. The SIE will test fundamental securities related knowledge, including knowledge of basic products, the structure and function of the securities industry, the regulatory agencies and their functions and regulated and prohibited practices, whereas the revised representative-level qualification examinations will test knowledge relevant to day-to-day activities, responsibilities and job functions of representatives. The SIE was developed in consultation with a committee of industry representatives and representatives of several other SROs. Each of the current representative-level examinations covers general securities knowledge, with the exception of the Research Analyst (Series 86 and 87) examinations.

The Exchange proposes to require that effective October 1, 2018, new applicants seeking to register in a representative capacity with the Exchange must pass the SIE examination [sic] before their registrations can become effective. The Exchange proposes to make the requirement operative on October 1, 2018 to coincide with the effective date of FINRA's requirement.

The Exchange notes that individuals who are registered as of October 1, 2018 are eligible to maintain their registrations without being subject to any additional requirements. Individuals who had been registered within the past two years prior to October 1, 2018, would also be eligible to maintain those registrations without being subject to any additional requirements, provided they register within two years from the date of their last registration. However, with respect to an individual who is not registered on the effective date of the proposed rule change but was registered within the past two years prior to the effective date of the proposed rule change, the individual's SIE status in the CRD system would be administratively terminated if such individual does not register with the Exchange within four years from the date of the individual's last registration. The Exchange also notes that consistent with Interpretation and Policy .01(b) of Rule 2.5, the Exchange will consider waivers of the SIE alone or the SIE and the representative or principal-level examination(s) for Members who are seeking registration in a representative- or principal-level registration category.[4]

Lastly, the Exchange proposes to eliminate references in its rules to alternative foreign examination modules, along with specific references to the Series 17, 37 and 38 examinations. Particularly, the Exchange notes that FINRA recently announced it was eliminating the United Kingdom Securities Representative and the Canadian Securities Representative registration categories, along with the respective associated exams (*i.e.,* Series 17, Series 37 and Series 38).[5] FINRA also stated that it intended to provide individuals who are associated persons of firms and who hold foreign registrations an alternative, more flexible, process to obtain an Exchange representative-level registration.[6] The Exchange believes that there is sufficient overlap between the SIE and foreign qualification requirements to permit them to act as exemptions to the SIE. As such, the Exchange proposes to provide that individuals who are in good standing as representatives with the Financial Conduct Authority in the United Kingdom or with a Canadian stock exchange or securities regulator would be exempt from the requirement to pass the SIE, and thus would be required only to pass a specialized knowledge examination to register with the Exchange as a representative. The proposed approach would provide individuals with a United Kingdom or Canadian qualification more flexibility to obtain an Exchange representative-level registration. The Exchange notes that FINRA has adopted a similar rule.[7]

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.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable

[3] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[4] Pursuant to a Regulatory Services Agreement between FINRA and the Exchange, FINRA provides the Exchange certain exam waiver services in responding to exam waiver requests from Exchange Members.

[5] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[6] *Id.*

[7] *Id.*

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will improve the efficiency of the Exchange's examination requirements, without compromising the qualification standards, by eliminating duplicative testing of general securities knowledge on examinations. FINRA has indicated that the SIE was developed in an effort to adopt an examination that would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. The Exchange also notes that the introduction of the SIE and expansion of the pool of individuals who are eligible to take the SIE, has the potential of enhancing the pool of prospective securities industry professionals by introducing them to securities laws, rules and regulations and appropriate conduct before they join the industry in a registered capacity. Lastly, the Exchange notes adopting the SIE requirement is consistent with the requirement recently adopted by FINRA.[11]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change, which harmonizes its rules with recent rule changes adopted by FINRA and which is being filed in conjunction with similar filings by the other national securities exchanges, will reduce the regulatory burden placed on market participants engaged in trading activities across different markets. The Exchange believes that the harmonization of these registration requirements across the various markets will reduce burdens on competition by removing impediments to participation in the national market system and promoting competition among participants across the multiple national securities exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative on October 1, 2018 to coincide with the effective date of FINRA's proposed rule change on which the proposal is based.[14] The waiver of the operative delay would make the Exchange's qualification requirements consistent with those of FINRA at the same time that FINRA does. Therefore, the Commission believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposal operative on October 1, 2018.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal 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 No. SR–CboeEDGA–2018–015 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 No. SR–CboeEDGA–2018–015. 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 filing will also 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 No. SR–CboeEDGA–2018–015 and should

[10] *Id.*

[11] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] *See supra* note 5.

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

be submitted on or before October 11, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20438 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33228; File No. 812–14875]

Exact Sciences Corporation

September 14, 2018.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under Section 3(b)(2) of the Investment Company Act of 1940 (''Act'').

Applicant: Exact Sciences Corporation.

Summary of Application: Applicant seeks an order under Section 3(b)(2) of the Act declaring it to be primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities. Applicant is in the business of producing and developing screening and diagnostic tests for the early detection and prevention of certain cancers.

Filing Dates: The application was filed on January 30, 2018 and amended on June 1, 2018, July 6, 2018 and August 24, 2018.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 10, 2018 and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. Applicant, 441 Charmany Drive, Madison, Wisconsin 53719.

[16] 17 CFR 200.30–3(a)(12).

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel, at (202) 551–6840, or Nadya B. Roytblat, Assistant Chief Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicant's Representations

1. Formed in 1995, Applicant is a Delaware corporation that is in the business of developing, clinical testing, marketing and commercializing cancer and pre-cancer screening and diagnostic tests. Applicant currently manufactures a non-invasive, patient-friendly screening test called Cologuard and provides it to patients on a prescription-only basis through its clinical laboratory. Applicant is also currently working on the development of additional tests for other types of cancers.

2. Applicant states that companies in the heathcare sector such as itself generally need significant liquid capital to finance their operations and meet high production, commercialization and regulatory costs. Such companies often spend a significant proportion of their revenues on research and development (''R&D'') in order to bring a product to market and to bring products through the Food and Drug Administration's (''FDA'') approval process.

3. Applicant states that it currently depends on raised capital to finance operations and continued growth but ultimately seeks to generate cash from its operations to support its business. Applicant states that it has successfully raised capital to finance its operations and commercialization of Cologuard in large part through various public offerings of its debt and equity securities. Applicant seeks to preserve its capital and maintain liquidity, pending the use of such capital to support its business operations, by investing in short-term investment grade and liquid fixed income and money market instruments that earn competitive market returns and provide a low level of credit risk (''Capital Preservation Investments''). Applicant also, to a limited extent, makes strategic investments in companies that are complementary to its core business. Applicant's board of directors oversees Applicant's investment practices and defines the parameters for investment activities. Applicant does not invest in securities for short-term speculative purposes.

Applicant's Legal Analysis

1. Applicant seeks an order under Section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities and therefore is not an investment company as defined in the Act.

2. Section 3(a)(l)(A) of the Act defines the term ''investment company'' to include an issuer that is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities. Section 3(a)(l)(C) of the Act further defines an investment company as an issuer that is engaged or proposes to engage in the business of investing, reinvesting, owning, holding or trading in securities, and owns or proposes to acquire investment securities having a value in excess of 40% of the value of the issuer's total assets (exclusive of Government securities and cash items) on an unconsolidated basis. Section 3(a)(2) of the Act defines ''investment securities'' to include all securities except Government securities, securities issued by employees' securities companies, and securities issued by majority-owned subsidiaries of the owner which (a) are not investment companies and (b) are not relying on the exclusions from the definition of investment company in Section 3(c)(1) or Section 3(c)(7) of the Act. While Applicant states that it does not hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities, Applicant states that it consistently holds investment securities that exceed 40% of its total assets on an unconsolidated basis (exclusive of Government securities and cash items). Applicant states that it therefore falls within the definition of investment company under Section 3(a)(l)(C) of the Act.

3. Rule 3a–8 under the Act provides an exclusion from the definition of investment company if, among other factors, a company's R&D expenses are a substantial percentage of its total expenses for the last four fiscal quarters combined. While Applicant believes that it complies with the conditions of Rule 3a–8, Applicant is concerned that its R&D expenses, while substantial in absolute terms, may not be substantial as a ratio of overall expenses, particularly given the expense increase in connection with the commercialization of Cologuard. Applicant's R&D expenses as a ratio of

total expenses have declined from a high of 74% of total expenses in 2012 to approximately 11% of total expenses for year-end 2017 and 12% as of March 31, 2018. Applicant explains that since the FDA's approval of Cologuard, Applicant has devoted more resources to sales and marketing. Although Applicant's R&D expenses have generally increased or remained steady overtime, its overall expenses have disproportionately increased, causing a decline in the ratio of R&D expenses to overall expenses. While Applicant expects to increase funding for R&D for other products, it also expects to increase funding with respect to the commercialization of Cologuard. Thus, Applicant does not expect its additional funding for R&D to cause a significant increase in the ratio of R&D funding to overall expenses.

4. Section 3(b)(2) of the Act provides that, notwithstanding Section 3(a)(l)(C) of the Act, the Commission may issue an order declaring an issuer to be primarily engaged in a business other than that of investing, reinvesting, owning, holding, or trading in securities directly, through majority-owned subsidiaries, or controlled companies conducting similar types of businesses. Applicant requests an order under Section 3(b)(2) of the Act declaring that it is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities, and therefore is not an investment company as defined in the Act.

5. In determining whether an issuer is ''primarily engaged'' in a non-investment company business under Section 3(b)(2) of the Act, the Commission considers the following factors: (a) The company's historical development, (b) its public representations of policy, (c) the activities of its officers and directors, (d) the nature of its present assets, and (e) the sources of its present income.[1]

6. Applicant submits that it satisfies the criteria for issuance of an order under Section 3(b)(2) of the Act because Applicant is primarily engaged in the business of developing, testing, marketing and commercializing cancer and pre-cancer diagnostic screening tests and not in the business of investing, reinvesting, owning, holding or trading in securities.

a. *Historical Development.* Applicant states that since its inception in 1995 it has operated in the healthcare sector to develop and commercialize cancer and pre-cancer screening and diagnostic tests. Applicant has focused its strategic opportunities in developing a screening test for colorectal cancer, culminating in the development of Cologuard, which received FDA approval in 2014. Since 2014, Applicant has been engaged in sales and marketing Cologuard and has begun research and development on testing related to other types of cancers. Applicant has nine wholly-owned subsidiaries, each of which is an operating company integrally related to Applicant's business. Applicant has never sold any of its subsidiaries since inception.

b. *Public Representations of Policy.* Applicant states it has never made any public representations that would indicate that it is in any business other than developing and commercializing cancer screening technologies. Applicant represents that it has never held and does not now hold itself out as an investment company within the meaning of the Act. Applicant states that all annual reports, web postings, press releases and written communications issued by Applicant have related to its business as a cancer screening and diagnostics company. Applicant further states that its public representations make clear that shareholders invest in the Applicant's securities with the expectation of realizing gains from Applicant's development and commercialization of cancer-screening and diagnostic technologies and not from returns on an investment portfolio. Applicant's only public representations regarding its investment securities are those required to be disclosed in public filings with the Commission.

c. *Activities of Officers and Directors.* Applicant represents that its board of directors and officers devote substantially all of their time managing Applicant's business as a cancer screening and diagnostics company. Applicant states that its management and corporate governance structure is comprised of professionals with expertise in technology, science, medicine, life science/biotechnology, and government. Applicant states that day-to-day management of the Capital Preservation Investments is handled by external asset managers consistent with investment guidelines adopted by the Applicant's board of directors on an annual basis. Applicant states that while the board of directors may review strategic investments in companies that are complementary to the Applicant's business, these reviews are made for long-term business, not speculative investment strategies. None of the members of management or the board of directors, even when reviewing strategic investments, spends or proposes to spend more than 1% of his or her time on any securities investment activities on behalf of the Applicant. They, along with the Applicant's approximately 1,268 full-time employees, are dedicated to the production and commercialization of Cologuard and the development of new cancer screening and diagnostic products.

d. *Nature of Assets.* Applicant states that as of March 31, 2018, Applicant's investment securities constituted approximately 79% of its total assets (excluding Government securities and cash items) on an unconsolidated basis.[2] Furthermore, more than 99% of its investment securities consisted of Capital Preservation Investments. Applicant's remaining investment securities consist of a strategic investment in a company whose business is complementary to the Applicant's business. Applicant anticipates that its investment securities other than Capital Preservation Investments will not exceed 10% of its total unconsolidated assets (excluding Government securities and cash items) in the future. Applicant uses current assets, including its Capital Preservation Investments, to finance its continued R&D program and operations in connection with the commercialization of Cologuard.

e. *Sources of Income and Revenue.* Applicant represents that since its inception it has had net operating losses. It does, however, derive income from its investment securities.

Applicant states that, particularly given its commercialization of Cologuard, a review of its current sources of revenues provides a more accurate picture of its operating company status. Applicant states that, for the year ended December 31, 2017, Applicant had approximately $266 million of revenues attributable to Cologuard. For the three months ended March 31, 2018, Cologuard revenues were approximately $90.3 million. In contrast, Applicant earned $3.9 million in net investment income in 2017, and $3.7 million for the three months ended March 31, 2018, all derived from Capital Preservation Investments.[3] Applicant states that if investment income were compared to its revenues from Cologuard, it would account for less than 2%. Applicant states it does not expect its net investment income to exceed 2% of its revenues over the long term.

[1] *Tonopah Mining Company of Nevada,* 26 SEC 426, 427 (1947).

[2] Applicant states that none of its subsidiaries owns investment securities.

[3] Applicant states that it has not, and does not expect to, earn investment income from its strategic investment.

7. Applicant asserts that its historical development, its public representations of policy, the activities of its officers and directors, the nature of its assets and its sources of income and revenue, as discussed in the application, demonstrate that it is engaged primarily in a business other than that of investing, reinvesting, owning, holding or trading securities. Applicant thus asserts that it satisfies the criteria for issuing an order under Section 3(b)(2) of the Act.

Applicant's Conditions

Applicant agrees that any order granted pursuant to the application will be subject to the following conditions:

1. Applicant will continue to allocate and use its accumulated cash and investment securities for bona fide business purposes; and

2. Applicant will refrain from investing or trading in securities for short-term speculative purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20408 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84143; File No. SR–CboeBZX–2018–019]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 3, To List and Trade Shares of Eighteen ADRPLUS Funds of the Precidian ETFs Trust Under Rule 14.11(i), Managed Fund Shares

September 14, 2018.

I. Introduction

On March 5, 2018, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of eighteen ADRPLUS Funds of the Precidian ETFs Trust (''Trust''), under Exchange Rule 14.11(i) (''Managed Fund Shares''). The proposed rule change was published for comment in the **Federal Register** on March 21, 2018.[3] On April 25, 2018, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[4] Also on April 25, 2018, the Exchange filed Amendment No. 1 to the proposed rule change.[5] On May 17, 2018, the Exchange filed Amendment No. 2 to the proposed rule change.[6] On June 19, 2018, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change.[8] On August 14, 2018, the Exchange filed Amendment No. 3 to the proposed rule change.[9] The Commission has received no comments on the proposed rule change. This order grants approval of the proposed rule change, as modified by Amendment No. 3.

II. The Exchange's Description of the Proposal, as Modified by Amendment No. 3[10]

The Exchange proposes to list and trade the Shares under Exchange Rule 14.11(i), which governs the listing and trading of Managed Fund Shares. The Funds are a series of, and the Shares will be offered by, the Trust.[11] Precidian Funds LLC (''Adviser'') will serve as the investment adviser to the Funds.[12]

A. Description of the ADRPLUS Funds

According to the Exchange, each Fund seeks to provide investment results that correspond generally, before fees and expenses, to the price and yield performance of a particular American Depositary Receipt, hedged against

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 82881 (March 15, 2018), 83 FR 12449.

[4] *See* Securities Exchange Act Release No. 83102, 83 FR 19126 (May 1, 2018).

[5] Amendment No. 1, which amended and replaced the proposed rule change in its entirety, is available at: *https://www.sec.gov/comments/sr-cboebzx-2018-019/cboebzx2018019-3551361-162325.pdf.*

[6] Amendment No. 2, which amended and replaced the proposed rule change in its entirety, is available at: *https://www.sec.gov/comments/sr-cboebzx-2018-019/cboebzx2018019-3665011-162423.pdf.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 83467, 83 FR 29589 (June 25, 2018).

[9] In Amendment No. 3, which amended and replaced, in its entirety, the proposed rule change as modified by Amendment No. 2, the Exchange: (a) Specified that the derivatives in which the Funds may invest are over-the-counter (''OTC'') currency swaps; (b) corrected references to, and specified with greater particularity, the Exchange requirements the Funds would not meet; (c) deleted a representation that the Funds may not meet the requirement of Exchange Rule 14.11(i)(4)(C)(iv)(b) that the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional exposures); (d) modified a trading halt representation to state that the Exchange will also halt trading in the Shares where a market-wide trading halt is declared in the associated Unhedged ADR (as defined herein) and that trading in the Shares will remain halted until trading in the Unhedged ADR resumes; (e) represented that Shares of the Funds would meet and be subject to Exchange Rule 14.11(i)(2)(C); (f) stated that each Fund expects to invest in excess of 95% of its net assets in the Unhedged ADRs, and each Fund expects that the gross notional value of the Currency Hedge (as defined herein) would be equal to the value of the Unhedged ADRs, which would be approximately 50% of the weight of the portfolio (including gross notional exposures); (g) addressed policy concerns related to the Currency Hedge held by the Funds in excess of the limit as provided in the Exchange Rule 14.11(i)(4)(C)(v); (h) modified a representation to state that the Exchange will suspend trading and commence delisting proceedings pursuant to Exchange Rule 14.12 for the Shares if the Unhedged ADR held by a Fund has been suspended from trading or delisted by the Unhedged ADR's listing exchange; (i) stated that the Exchange or Financial Industry Regulatory Authority, Inc. (''FINRA''), on behalf of the Exchange, are able to access, as needed, trade information for certain fixed income instruments reported to the Trade Reporting and Compliance Engine (''TRACE''); (j) clarified a criterion regarding when an order to redeem creation units of a Fund would be deemed received by the distributor; (k) specified that the Information Circular (as discussed herein) will discuss how information regarding the Disclosed Portfolio (as defined in Exchange Rule 14.11(i)(3)(B)) is disseminated; and (l) made other non-substantive, technical, and clarifying corrections to the proposal. Because Amendment No. 3 clarifies the derivatives in which the Funds may invest, adds specificity to certain requirements, made additional representations, and otherwise does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues under the Act, Amendment No. 3 is not subject to notice and comment. Amendment No. 3 to the proposed rule change is available at: *https://www.sec.gov/comments/sr-cboebzx-2018-019/cboebzx2018019-4290642-173190.pdf.*

[10] Additional information regarding the Funds, the Trust, and the Shares can be found in Amendment No. 3 and the Registration Statement. *See supra* note 9 and *infra* note 11.

[11] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). *See* Registration Statement on Form N–1A for the Trust, dated June 14, 2017 (File Nos. 333–171987 and 811–22524) (''Registration Statement''). In addition, the Exchange states that the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 32622 (May 2, 2017) (File No. 812–14584).

[12] The Exchange represents that the Adviser is not a registered broker-dealer and is not affiliated with a broker-dealer. In addition, Adviser personnel who make decisions regarding a Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. The Exchange states that in the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

fluctuations in the exchange rate between the U.S. dollar and the local currency of the foreign security underlying the American Depositary Receipt (''Local Currency''). For example, the Anheuser-Busch InBev SA/NV ADRPLUS Fund seeks to provide investment results that correspond generally, before fees and expenses, to the price and yield performance of Anheuser-Busch InBev SA/NV (ADR), hedged against fluctuations in the exchange rate between the U.S. dollar and the euro. The following chart includes the underlying company and the Local Currency for each of the Funds.

Fund name	Underlying company	Local currency
Anheuser-Busch InBev SA/NV ADRPLUS Fund	Anheuser-Busch InBev SA/NV	Euro.
AstraZeneca PLC ADRPLUS Fund	AstraZeneca PLC	British pound.
Banco Santander, S.A. ADRPLUS Fund	Banco Santander, S.A	Euro.
BP P.L.C. ADRPLUS Fund	BP p.l.c	British pound.
British American Tobacco p.l.c. ADRPLUS Fund	British American Tobacco p.l.c	British pound.
Diageo plc ADRPLUS Fund	Diageo plc	British pound.
GlaxoSmithKline plc ADRPLUS Fund	GlaxoSmithKline plc	British pound.
HSBC Holdings Plc ADRPLUS Fund	HSBC Holdings Plc	British pound.
Mitsubishi UFJ Financial Group, Inc. ADRPLUS Fund	Mitsubishi UFJ Financial Group, Inc	Japanese yen.
Novartis AG ADRPLUS Fund	Novartis AG	Swiss franc.
Novo Nordisk A/S (B Shares) ADRPLUS Fund	Novo Nordisk A/S (B Shares)	Danish krone.
Royal Dutch Shell plc (Class A) ADRPLUS Fund	Royal Dutch Shell plc (Class A)	Euro.
Royal Dutch Shell plc (Class B) ADRPLUS Fund	Royal Dutch Shell plc (Class B)	British pound.
Sanofi ADRPLUS Fund	Sanofi	Euro.
SAP AG ADRPLUS Fund	SAP AG	Euro.
Total S.A. ADRPLUS Fund	Total S.A	Euro.
Toyota Motor Corporation ADRPLUS Fund	Toyota Motor Corporation	Japanese yen.
Vodafone Group Plc ADRPLUS Fund	Vodafone Group Plc	British pound.

According to the Exchange, each Fund will hold only: (i) Shares of an American Depositary Receipt (''Unhedged ADR'') listed on a U.S. national securities exchange; (ii) OTC currency swaps that hedge against fluctuations in the exchange rate between the U.S. dollar and the Local Currency (''Currency Hedge''); and (iii) cash and cash equivalents.[13]

The Trust is required to comply with Rule 10A–3 under the Act [14] for the initial and continued listing of the Shares of each Fund. In addition, the Exchange represents that the Shares of each Fund will meet and be subject to all other requirements of the Generic Listing Standards, as defined below, and other applicable continued listing requirements for Managed Fund Shares under Exchange Rule 14.11(i), such as the listing requirements regarding the Disclosed Portfolio (including the requirement that the Disclosed Portfolio and the net asset value (''NAV'') will be made available to all market participants at the same time); [15] and the requirements regarding intraday indicative value,[16] suspension of trading or removal,[17] trading halts,[18] disclosure,[19] firewalls,[20] and surveillance.[21] Further, at least 100,000 Shares of each Fund will be outstanding upon the commencement of trading.[22]

B. The Exchange's Policy Discussion

According to the Exchange, the Funds will provide investors with the opportunity to easily eliminate currency exposure that they may not even realize exists with Unhedged ADRs without having to transact in the currency derivatives market. The Exchange believes that this would confer a significant benefit to investors and the broader marketplace by adding transparency and simplifying the process of eliminating risk from an investor's portfolio.

The Exchange believes that while the Funds would not meet the generic listing standards for Managed Fund Shares (''Generic Listing Standards''), in particular Exchange Rules 14.11(i)(4)(C)(i)(a)(3)–(4) [23] and 14.11(i)(4)(C)(v),[24] the policy issues that those rules are intended to address are otherwise mitigated by the structure, holdings, and purpose of the Funds.[25] According to the Exchange, Exchange Rule 14.11(i)(4)(C)(i)(a)(3) is intended to ensure that no single equity security constitutes too concentrated of a position in a series of Managed Fund Shares, and Exchange Rule 14.11(i)(4)(C)(i)(a)(4) is similarly intended to diversify the holdings of a series of Managed Fund Shares. The Exchange believes that these policy concerns are mitigated as they relate to the Funds because: (i) The Unhedged ADR will meet the market cap and liquidity requirements of Exchange Rules 14.11(i)(4)(C)(i)(a)(1) and (2); and

[13] For purposes of this filing and consistent with Exchange Rule 14.11(i)(4)(C)(iii), cash equivalents are short-term instruments with maturities of less than three months that include only the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

[14] 17 CFR 240.10A–3.

[15] *See* Exchange Rules 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[16] *See* Exchange Rule 14.11(i)(4)(B)(i).

[17] *See* Exchange Rule 14.11(i)(4)(B)(iii).

[18] *See* Exchange Rule 14.11(i)(4)(B)(iv). The Exchange will also halt trading in a Fund where a market-wide trading halt is declared in the associated Unhedged ADR and trading in the Fund will remain halted until trading in the Unhedged ADR resumes.

[19] *See* Exchange Rule 14.11(i)(6).

[20] *See* Exchange Rule 14.11(i)(7).

[21] *See* Exchange Rule 14.11(i)(2)(C).

[22] *See* Exchange Rule 14.11(i)(4)(A)(i).

[23] The Exchange represents that the Funds will not meet: (i) The requirement under Exchange Rule 14.11(i)(4)(C)(i)(a)(3) that the most heavily weighted component stock shall not exceed 30% of the equity weight of the portfolio; and (ii) the requirement under Exchange Rule 14.11(i)(4)(C)(i)(a)(4) that the equity portion of the portfolio shall include a minimum of 13 component stocks.

[24] The Exchange represents that the Funds may not meet the requirement under Exchange Rule 14.11(i)(4)(C)(v) that the aggregate gross notional value of OTC derivatives shall not exceed 20% of the weight of the portfolio (including gross notional exposures).

[25] The Exchange represents that each Fund expects to invest in excess of 95% of its net assets in the Unhedged ADRs. Each Fund expects that the gross notional value of the Currency Hedge would be equal to the value of the Unhedged ADRs, which would be approximately 50% of the weight of the portfolio (including gross notional exposures).

(ii) the intended function of the Funds is to eliminate currency exposure risk for a single security, which means that the Funds are necessarily concentrated. The Exchange also believes that the creation and redemption mechanism will provide a near frictionless arbitrage opportunity that would minimize the risk of manipulation of either the Unhedged ADR or the applicable Fund and, thus, mitigate the manipulation concerns that Exchange Rules 14.11(i)(4)(C)(i)(a)(3) and (4) were intended to address. According to the Exchange, the policy issues that Exchange Rule 14.11(i)(4)(C)(v) is intended to address are also mitigated by the way that the Funds would use OTC currency swaps. The Exchange states that the rule is intended to mitigate concerns regarding the manipulability of a particular underlying reference asset or derivatives contract and to minimize counterparty risk. While the Currency Hedge positions taken by the Funds would not meet the Generic Listing Standards related to OTC derivatives holdings, the Exchange believes that the policy concerns about limiting exposure to potentially manipulable underlying reference assets that the Generic Listing Standards are intended to address are otherwise mitigated by the liquidity in the underlying spot currency market. The Exchange represents that the Funds will attempt to limit counterparty risk in OTC currency swaps by: (i) Entering into such contracts only with counterparties the Advisor believes are creditworthy; (ii) limiting a Fund's exposure to each counterparty; and (iii) monitoring the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis. The Exchange believes that counterparty risk associated with OTC currency swaps is further mitigated because the currency swaps are settled on a daily basis and, thus, the counterparty risk for any particular swap is limited in two ways—first, counterparty credit exposure is always limited to a 24 hour period and, second, the exposure of the swap is only to the movement in the currencies over that same 24 hour period.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares, as modified by Amendment No. 3, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[26] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[27] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act [28] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers and investors of information with respect to quotations for and transactions in securities. As noted above, each Fund will comply with the requirements for Managed Fund Shares under Exchange Rule 14.11(i) related to Disclosed Portfolio, NAV (including the requirement that the Disclosed Portfolio and the NAV will be made available to all market participants at the same time), and the intraday indicative value. The intraday, closing and settlement prices of exchange-traded portfolio assets, which include only Unhedged ADRs, will be readily available from the securities exchanges on which such Unhedged ADRs are traded, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. Intraday price quotations on OTC currency swaps are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay or in real-time for a paid fee. Price information for cash equivalents will be available from major market data vendors. Each Fund's Disclosed Portfolio will be available on the issuer's website (*www.precidian.com*) free of charge. Information regarding market price and trading volume of the Shares will be continuously available throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume for the Shares will be published daily in the financial section of newspapers. Each Fund's website will include the prospectus for the applicable Fund and additional information related to NAV and other applicable quantitative information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. Trading in the Shares may be halted for market conditions or for reasons that, in the view of the Exchange, make trading inadvisable. The Exchange will also halt trading in a Fund where a market-wide trading halt is declared in the associated Unhedged ADR, and trading in the Fund will remain halted until trading in the Unhedged ADR resumes.

In addition, the Exchange represents that the Adviser is not a registered broker-dealer and is not affiliated with a broker-dealer.[29]

Trading in the Shares will be subject to the Exchange's surveillance procedures, which are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. The Exchange represents that trading in the Shares will be subject to the Exchange's existing rules governing the trading of equity securities.

All Unhedged ADRs will be listed on a U.S. national securities exchange, all of which are members of the Intermarket Surveillance Group (''ISG'') or are exchanges with which the Exchange has in place a comprehensive surveillance

[26] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 15 U.S.C. 78f(b)(5).

[28] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[29] *See supra* note 12. The Commission also notes that that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

sharing agreement.[30] The Exchange may obtain information regarding trading in the Funds and Unhedged ADRs held by each Fund via the ISG, from other exchanges that are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. Additionally, the Exchange or FINRA, on behalf of the Exchange, are able to access, as needed, trade information for certain fixed income instruments reported to TRACE.

The Exchange represents that it deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made the following representations:

(1) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(2) Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares, and these procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws.

(3) Each of the Funds will hold only: (i) Shares of an Unhedged ADR listed on a U.S. national securities exchange; (ii) OTC currency swaps that hedge against fluctuations in the exchange rate between the U.S. dollar and the Local Currency; and (iii) cash and cash equivalents.

(4) The U.S. national securities exchanges on which the Unhedged ADRs will be listed are members of ISG or are exchanges with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange may obtain information regarding trading in the Funds and Unhedged ADRs held by each Fund via the ISG, from other exchanges that are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. Additionally, the Exchange or FINRA, on behalf of the Exchange, are able to access, as needed, trade information for certain fixed income instruments reported to TRACE.

(5) The Funds will attempt to limit counterparty risk in OTC currency swaps by: (i) Entering into such contracts only with counterparties the Advisor believes are creditworthy; (ii) limiting a Fund's exposure to each counterparty; and (iii) monitoring the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis.

(6) Other than Exchange Rules 14.11(i)(4)(C)(i)(a)(3)–(4) and 14.11(i)(4)(C)(v), the Shares of each Fund will meet and be subject to all requirements of the Generic Listing Standards and other applicable continued listing requirements for Managed Fund Shares under Exchange Rule 14.11(i), such as the listing requirements regarding the Disclosed Portfolio (including the requirement that the Disclosed Portfolio and NAV will be made available to all market participants at the same time); and the requirements regarding intraday indicative value, suspension of trading or removal, trading halts, disclosure, firewalls, and surveillance.

(7) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (i) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (ii) Exchange Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the intraday indicative value and Disclosed Portfolio is disseminated; (iv) the risks involved in trading the Shares during the Pre-Opening and After Hours Trading Sessions when an updated intraday indicative value will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information.

(8) The Exchange will suspend trading and commence delisting proceedings pursuant to Exchange Rule 14.12 for a Fund if the Unhedged ADR held by a Fund has been suspended from trading or delisted by the Unhedged ADR's listing exchange.

(9) The Trust is required to comply with Rule 10A–3 under the Act[31] for the initial and continued listing of the Shares of each Fund.

(10) A minimum of 100,000 Shares for each Fund will be outstanding at the commencement of trading on the Exchange.

In addition, the Exchange represents that all statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of reference assets and intraday indicative values, and the applicability of Exchange listing rules specified in this filing shall constitute continued listing requirements for the Funds. In addition, the Trust, on behalf of the Funds, has represented to the Exchange that it will advise the Exchange of any failure by a Fund or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If a Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

This approval order is based on all of the Exchange's representations, including those set forth above and in Amendment No. 3. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 3, is consistent with Section 6(b)(5) of the Act[32] and Section 11A(a)(1)(C)(iii) of the Act[33] and the rules and regulations thereunder applicable to a national securities exchange.[34]

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[35] that the proposed rule change (SR–CboeBZX–2018–019), as modified by Amendment No. 3, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20432 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

[30] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.* The Exchange notes that not all components of the Disclosed Portfolio for a Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[31] 17 CFR 240.10A–3.

[32] 15 U.S.C. 78f(b)(5).

[33] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[34] As noted above, on June 19, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change. No comments were received in connection with that order instituting proceedings. *See supra* note 7.

[35] 15 U.S.C. 78s(b)(2).

[36] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84142; File No. SR–CBOE–2018–064]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Rules Relating to Categories of Registration and Respective Qualification Examinations Required for Trading Permit Holders (''TPHs'') and Associated Persons That Engage in Trading Activities on the Exchange

September 14, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 7, 2018, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The 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 Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its rules relating to categories of registration and respective qualification examinations required for Trading Permit Holders (''TPHs'') and associated persons that engage in trading activities on the Exchange.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The SEC recently approved a proposed rule change to restructure the FINRA representative-level qualification examination program.[3] The rule change, which will become effective on October 1, 2018, restructures the examination program into a more efficient format whereby all new representative-level applicants will be required to take a general knowledge examination (the Securities Industry Essentials Examination (''SIE'')) and a tailored, specialized knowledge examination (a revised representative-level qualification examination) for their particular registered role. Individuals are not required to be associated with an Exchange or any other self-regulatory organization (''SRO'') member to be eligible to take the SIE. However, passing the SIE alone will not qualify an individual for registration with the Exchange. To be eligible for registration, an individual must also be associated with a firm, pass an appropriate qualification examination for a representative or principal and satisfy the other requirements relating to the registration process.

The SIE would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. In particular, the SIE will cover four major areas. The first, ''Knowledge of Capital Markets,'' focuses on topics such as types of markets and offerings, broker-dealers and depositories, and economic cycles. The second, ''Understanding Products and Their Risks,'' covers securities products at a high level as well as associated investment risks. The third, ''Understanding Trading, Customer Accounts and Prohibited Activities,'' focuses on accounts, orders, settlement and prohibited activities. The final area, ''Overview of the Regulatory Framework,'' encompasses topics such as SROs, registration requirements and specified conduct rules. It's anticipated that the SIE would include 75 scored questions plus an additional 10 unscored pretest questions. The passing score would be determined through methodologies compliant with testing industry standards used to develop examinations and set passing standards.

The restructured program eliminates duplicative testing of general securities knowledge on the current representative-level qualification examinations by moving such content into the SIE. The SIE will test fundamental securities related knowledge, including knowledge of basic products, the structure and function of the securities industry, the regulatory agencies and their functions and regulated and prohibited practices, whereas the revised representative-level qualification examinations will test knowledge relevant to day-to-day activities, responsibilities and job functions of representatives. The SIE was developed in consultation with a committee of industry representatives and representatives of several other SROs. Each of the current representative-level examinations covers general securities knowledge, with the exception of the Research Analyst (Series 86 and 87) examinations.

The Exchange proposes to require that effective October 1, 2018, new applicants seeking to register in a representative capacity with the Exchange must pass the SIE before their registrations can become effective. The Exchange proposes to make the requirement operative on October 1, 2018 to coincide with the effective date of FINRA's requirement.

The Exchange notes that individuals who are registered as of October 1, 2018 are eligible to maintain their registrations without being subject to any additional requirements. Individuals who had been registered within the past two years prior to October 1, 2018, would also be eligible to maintain those registrations without being subject to any additional requirements, provided they register within two years from the date of their last registration. However, with respect to an individual who is not registered on the effective date of the proposed rule change but was registered within the past two years prior to the effective date of the proposed rule change, the individual's SIE status in the CRD system would be administratively terminated if such individual does not register with the Exchange within four years from the date of the individual's last registration. The Exchange also notes that consistent with Interpretation and Policy .05 of Rule 3.6A, the Exchange will consider waivers of the SIE alone or the SIE and the representative or principal-level examination(s) for TPHs who are

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

seeking registration in a representative- or principal-level registration category.[4]

Lastly, the Exchange proposes to adopt Interpretation and Policy .09 of Rule 3.6A and Interpretation and Policy .02 of Rule 9.3 to provide individuals who are associated persons of firms and who hold foreign registrations an alternative, more flexible, process to obtain an Exchange representative-level registration. The Exchange believes that there is sufficient overlap between the SIE and these foreign qualification requirements to permit them to act as exemptions to the SIE. As such the Exchange proposes to provide that individuals who are in good standing as representatives with the Financial Conduct Authority in the United Kingdom or with a Canadian stock exchange or securities regulator would be exempt from the requirement to pass the SIE, and thus would be required only to pass a specialized knowledge examination to register with the Exchange as a representative. The proposed approach would provide individuals with a United Kingdom or Canadian qualification more flexibility to obtain an Exchange representative-level registration. The Exchange notes that FINRA has adopted a similar rule.[5]

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.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change will improve the efficiency of the Exchange's examination requirements, without compromising the qualification standards, by eliminating duplicative testing of general securities knowledge on examinations. FINRA has indicated that the SIE was developed in an effort to adopt an examination that would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. The Exchange also notes that the introduction of the SIE and expansion of the pool of individuals who are eligible to take the SIE, has the potential of enhancing the pool of prospective securities industry professionals by introducing them to securities laws, rules and regulations and appropriate conduct before they join the industry in a registered capacity. Lastly, the Exchange notes adopting the SIE requirement is consistent with the requirement recently adopted by FINRA.[9]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change, which harmonizes its rules with recent rule changes adopted by FINRA and which is being filed in conjunction with similar filings by the other national securities exchanges, will reduce the regulatory burden placed on market participants engaged in trading activities across different markets. The Exchange believes that the harmonization of these registration requirements across the various markets will reduce burdens on competition by removing impediments to participation in the national market system and promoting competition among participants across the multiple national securities exchanges.

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 written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative on October 1, 2018 to coincide with the effective date of FINRA's proposed rule change on which the proposal is based.[12] The waiver of the operative delay would make the Exchange's qualification requirements consistent with those of FINRA. Therefore, the Commission believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposal operative on October 1, 2018.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing,

[4] Pursuant to a Regulatory Services Agreement between FINRA and Cboe Options, FINRA provides Cboe Options certain exam waiver services in responding to exam waiver requests from Cboe Options TPHs.

[5] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] *See* Securities Exchange Act Release No. 81098 (July 7, 2017), 82 FR 32419 (July 13, 2017) (Order Approving File No. SR–FINRA–2017–007).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] *See supra* note 3.

[13] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2018–064 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2018–064. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2018–064 and should be submitted on or before October 11, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20433 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84130; File No. SR–ICC–2018–007]

Self-Regulatory Organizations; ICE Clear Credit LLC; Order Approving Proposed Rule Change Relating to the Clearance of an Additional Credit Default Swap Contract

September 14, 2018.

I. Introduction

On June 13, 2018, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 [1] and Rule 19b–4 thereunder,[2] a proposed rule change to revise the ICC Rulebook (the ''Rules'') [3] to provide for the clearance of an additional Standard Emerging Market Sovereign CDS contract (''EM Contract''). The proposed rule change was published for comment in the **Federal Register** on July 3, 2018.[4] The Commission did not receive comments regarding the proposed rule change. On August 16, 2018, the Commission designated a longer period for Commission action on the proposed rule change.[5] For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

The proposed rule change will provide the basis for ICC to clear an additional credit default swap contract. ICC proposes to amend Subchapter 26D of its Rules to provide for the clearance of an additional EM Contract, the Lebanese Republic. ICC represents that this additional EM Contract has terms consistent with the other EM Contracts approved for clearing at ICC and is governed by Subchapter 26D of the Rules.[6] Minor revisions to Subchapter 26D (Standard Emerging Market Sovereign (''SES'') Single Name) are being made to provide for clearing the additional EM Contract. Specifically, in Rule 26D–102 (Definitions), ''Eligible SES Reference Entities'' is modified to include the Lebanese Republic in the list of specific Eligible SES Reference Entities to be cleared by ICC. ICC has also represented that clearing of the additional EM Contract will not require any changes to ICC's Risk Management Framework or other policies and procedures constituting rules within the meaning of the Securities Exchange Act of 1934 (''Act'').[7]

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[8] Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, assure the safeguarding of securities and funds which are in the custody or control of the clearing agency for which it is responsible and, in general, to protect investors and the public interest.[9]

The Commission finds that the rule change is consistent with Section 17A(b)(3)(F) of the Act [10] and the rules and regulations thereunder applicable to ICC. The Commission has reviewed the terms and conditions of this contract and has determined that it is substantially similar to the other contracts listed in Subchapter 26D of the ICC Rules, all of which ICC currently clears, the key difference being that the underlying reference obligations will be issuances by the Lebanese Republic. Moreover, after reviewing the Notice and ICC's Rules, policies and procedures, the Commission finds that the additional EM Contract will be cleared pursuant to ICC's existing clearing arrangements and related financial safeguards, protections and risk management procedures.[11] In addition, based on its own experience and expertise, including a review of data on volume, open interest, and the number of ICC clearing participants (''CPs'') that currently trade in the additional EM Contract as well as certain model parameters for the additional EM Contract, the Commission finds that ICC's rules, policies, and procedures are reasonably designed to price and measure the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms used herein but not otherwise defined have the meaning set forth in the ICC Rules. Available at *https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Rules.pdf.*

[4] Securities Exchange Act Release No. 34–83545 (June 28, 2018), 83 FR 31244 (July 3, 2018) (SR–ICC–2018–007) (''Notice'').

[5] Securities Exchange Act Release No. 34–83864 (August 16, 2018), 83 FR 42540 (August 22, 2018) (SR–ICC–2018–007).

[6] Notice, 83 FR at 31245.

[7] Id.

[8] 15 U.S.C. 78s(b)(2)(C).

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 78q–1.

[11] Notice, 83 FR at 31245.

potential risk presented by this product, collect financial resources in proportion to such risk, and liquidate this product in the event of a CP default, all of which should help ensure ICC's ability to maintain the financial resources it needs to provide its critical services and function as a central counter party, thereby promoting the prompt and accurate settlement of EM Contracts and other credit default swap transactions. For the same reasons, the Commission believes that the rule change would help assure the safeguarding of securities or funds in the custody or control of ICC, and would be consistent with the protection of investors and the public interest.

Therefore, the Commission finds that acceptance of the additional EM Contract, on the terms and conditions set out in ICC's Rules, is consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[12]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act,[13] and the rules and regulations thereunder.

It is therefore ordered pursuant to Section 19(b)(2) of the Act[14] that the proposed rule change (SR–ICC–2018–007) be, and hereby is, approved.[15]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20434 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84127; File No. SR–FINRA–2018–034]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2360 (Options) To Increase Position Limits on Options on Certain Exchange-Traded Funds

September 14, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 31, 2018, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 2360 (Options) to increase the position limit for conventional options on the following exchange-traded funds (''ETF''): The Standard and Poor's Depositary Receipts Trust (''SPY''), iShares Russell 2000 ETF (''IWM''), PowerShares QQQ Trust (''QQQ''), iShares MSCI Emerging Markets ETF (''EEM''), iShares China Large-Cap ETF (''FXI''), iShares MSCI EAFE ETF (''EFA''), iShares MSCI Brazil Capped ETF (''EWZ''), iShares 20+ Year Treasury Bond Fund ETF (''TLT''), and iShares MSCI Japan ETF (''EWJ'').

Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

2360. Options

(a) No Change.

(b) Requirements

(1) through (2) No Change.

(3) Position Limits

(A) Stock Options—

(i) through (ii) No Change.

(iii) Conventional Equity Options

a. For purposes of this paragraph (b), standardized equity option contracts of the put class and call class on the same side of the market overlying the same security shall not be aggregated with conventional equity option contracts or FLEX Equity Option contracts overlying the same security on the same side of the market. Conventional equity option contracts of the put class and call class on the same side of the market overlying the same security shall be subject to a position limit of:

1. through 5. No Change.

6. for selected conventional options on exchange-traded funds (''ETF''), the position limits are listed in the chart below:

Security underlying option	Position limit
The DIAMONDS Trust (DIA)	300,000 contracts.
The Standard and Poor's Depositary Receipts Trust (SPY)	[900,000]*1,800,000* contracts.
The iShares Russell 2000 [Index Fund]*ETF* (IWM)	[500,000]*1,000,000* contracts.
The PowerShares QQQ Trust (QQQ[Q])	[900,000]*1,800,000* contracts.
The iShares MSCI Emerging Markets [Index Fund]*ETF* (EEM)	[500,000]*1,000,000* contracts.
iShares China Large-Cap ETF (FXI)	*500,000 contracts.*
iShares MSCI EAFE ETF (EFA)	*500,000 contracts.*
iShares MSCI Brazil Capped ETF (EWZ)	*500,000 contracts.*
iShares 20+ Year Treasury Bond Fund ETF (TLT)	*500,000 contracts.*
iShares MSCI Japan ETF (EWJ)	*500,000 contracts.*

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 15 U.S.C. 78q–1.

[14] 15 U.S.C. 78s(b)(2).

[15] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

b. No Change.
(B) through (D) No Change.
(4) through (24) No Change.
(c) No Change.

• • • **Supplementary Material:——**

.01 through .03 No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA 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. FINRA 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

FINRA Rule 2360(b)(3)(A) imposes a position limit on the number of equity options contracts in each class on the same side of the market that can be held or written by a member, a person associated with a member, or a customer or a group of customers acting in concert. Position limits are intended to prevent the establishment of options positions that can be used to manipulate or disrupt the underlying market or might create incentives to manipulate or disrupt the underlying market so as to benefit the options position. In addition, position limits serve to reduce the potential for disruption of the options market itself, especially in illiquid options classes.[4] This consideration has been balanced by the concern that the limits ''not be established at levels that are so low as to discourage participation in the options market by institutions and other investors with substantial hedging needs or to prevent specialists and market makers from adequately meeting their obligations to maintain a fair and orderly market.'' [5]

Rule 2360(b)(3)(A)(i) does not independently establish a position limit for standardized equity options. Rather, the position limit established by the rules of an options exchange for a particular equity option is the applicable position limit for purposes of Rule 2360.[6] Rule 2360(b)(3)(A)(iii) provides that conventional equity options are subject to a basic position limit of 25,000 contracts or a higher tier for conventional option contracts on securities that underlie exchange-traded options qualifying for such higher tier as determined by the rules of the options exchanges. In addition, FINRA lists position limits for options on securities that have higher position limits—currently, only the ETFs listed in Rule 2360(b)(3)(A)(iii)a.6.—that also generally mirror the options exchange position limits.[7] At this time, FINRA proposes to conform to the options exchanges' recent amendments that increased (or in the case of SPY decreased from the pilot program) the position limit options on the following ETFs: SPY, IWM, QQQ, EEM, FXI, EFA, EWZ, TLT and EWJ.[8]

The proposed rule change would amend the table provided in Rule 2360(b)(3)(A)(iii)a.6. as follows:

- The position limits for options on SPY would be increased from 900,000 contracts to 1,800,000 contracts;
- The position limit for options on IWM would be increased from 500,000 contracts to 1,000,000 contracts;
- The position limit for options on QQQ would be increased from 900,000 contracts to 1,800,000 contracts; and
- The position limit for options on EEM would be increased from 500,000 contracts to 1,000,000 contracts.

In addition, the proposed rule change would add to the table provided in Rule 2360(b)(3)(A)(iii)a.6. as follows, with the effect of each ETF being increased from the current position limit of 250,000 contracts:

- The position limit for options on FXI would be increased to 500,000 contracts;
- The position limit for options on EFA would be increased to 500,000 contracts;
- The position limit for options on EWZ would be increased to 500,000 contracts;
- The position limit for options on TLT would be increased to 500,000 contracts; and
- The position limit for options on EWJ would be increased to 500,000 contracts.[9]

In support of the proposed rule change, as noted by Cboe, position limits are determined by the option exchange's requirements according to the number of outstanding shares and the trading volume of the underlying ETF over the past six months.[10] The ETFs that underlie options subject to the proposed rule change are highly liquid, and are based on a broad set of highly liquid securities and other reference assets. The above listed ETFs are listed on various national securities exchanges and meet their listing standards.

FXI tracks the performance of the FTSE China 50 Index, which is composed of the 50 largest Chinese stocks.[11] EEM tracks the performance of

[4] *See* Securities Exchange Act Release No. 40969 (January 22, 1999), 64 FR 4911, 4912–4913 (February 1, 1999) (Order Approving File No. SR–CBOE–98–23) (citing H.R. No. IFC–3, 96th Cong., 1st Sess. at 189–91 (Comm. Print 1978)).

[5] *Id.* at 4913.

[6] *See e.g.,* CBOE Rule 4.11; ISE Rule 412; NASDAQ PHLX Rule 1001; NYSE American Rule 904; NYSE Arca Rule 6.8; MIAX Rule 307; BOX Rule 3120 and IM–3120–2; Nasdaq Chapter III, Section 7; BX Chapter III, Section 7; and BZX Rule 18.7.

[7] The options exchanges have recently revised the position limit on SPY options to 1,800,000 contracts after expiration of a pilot program on July 12, 2018 that eliminated position limits on SPY options. FINRA retained its position for conventional options on SPY at 900,000 contracts. The proposed rule change proposes to increase the position limit on SPY to 1,800,000 consistent with the options exchanges updating the position limit on SPY to 1,800,000 contracts. *See* Securities Exchange Act Release No. 83349 (May 30, 2018), 83 FR 26123 (June 5, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–MIAX–2018–11). *See also* Securities Exchange Act Release No. 83412 (June 12, 2018), 83 FR 28298 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–PHLX–2018–44); Securities Exchange Act Release No. 83414 (June 12, 2018), 83 FR 28296 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–BOX–2018–22); Securities Exchange Act Release No. 83415 (June 12, 2018), 83 FR 28274 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–CBOE–2018–042); Securities Exchange Act Release No. 83413 (June 12, 2018), 83 FR 28277 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEArca-2018–44); and Securities Exchange Act Release No. 83417 (June 12, 2018), 83 FR 28279 (June 18, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEAMER–2018–26).

[8] *See* note 7 for discussion regarding position limits for options on SPY. *See also* Securities Exchange Act Release No. 82770 (February 23, 2018), 83 FR 8907 (March 1, 2018) (Order Granting Accelerated Approval of File No. SR–CBOE–2017–057). *See also* Securities Exchange Act Release No. 82931 (March 22, 2018), 83 FR 13323 (March 28, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–MIAX–2018–10); Securities Exchange Act Release No. 82930 (March 22, 2018), 83 FR 13330 (March 28, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–BOX–2018–10); Securities Exchange Act Release No. 82932 (March 22, 2018), 83 FR 13316 (March 28, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–PHLX–2018–24); Securities Exchange Act Release No. 83066 (April 19, 2018), 83 FR 18099 (April 25, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEArca-2018–23) and Securities Exchange Act Release No. 83065 (April 19, 2018), 83 FR 18093 (April 25, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSEAMER–2018–14).

[9] The proposed rule filing would also make certain wording changes to the listing of the names of the ETFs and change in two places ''Index Fund'' to ''ETF''. The proposed rule filing would also revise the symbol of The PowerShares QQQ Trust to ''QQQ.''

[10] See for example, Cboe Rule 4.11 Interpretations and Policies: .02.

[11] *See https://www.ishares.com/us/products/239536/ishares-china-largecap-etf.*

the MSCI Emerging Markets Index, which is composed of approximately 800 component securities from emerging market countries from all over the world.[12] IWM tracks the performance of the Russell 2000 Index, which is composed of 2,000 small-cap domestic stocks.[13] EFA tracks the performance of MSCI EAFE Index, which has over 900 component securities.[14] The MSCI EAFE Index is designed to represent the performance of large and mid-cap securities across 21 developed markets, including countries in Europe, Australia and the Far East, excluding the U.S. and Canada.[15] EWZ tracks the performance of the MSCI Brazil 25/50 Index, which is composed of shares of large and mid-size companies in Brazil.[16] TLT tracks the performance of ICE U.S. Treasury 20+ Year Bond Index, which is composed of long-term U.S. Treasury bonds.[17] QQQ tracks the performance of the Nasdaq-100 Index, which is composed of 100 of the largest domestic and international non-financial companies listed on the Nasdaq Stock Market LLC (''Nasdaq'').[18] EWJ tracks the MSCI Japan Index, which tracks the performance of large and mid-sized companies in Japan.[19] SPY tracks the performance of the S&P 500® Index, which is an index of diversified large cap U.S. companies.[20]

In support of this proposal, all trading and other statistics, except SPY which were compiled by FINRA, have been compiled by Cboe as of the dates provided by Cboe and provided in its proposed rule change to increase the applicable positions limits:[21]

ETF	2017 ADV (mil. shares)	2017 ADV (option contracts)	Shares outstanding (mil.)	Fund market cap. ($mil.)
FXI	15.08	71,944	78.6	$3,343.6
EEM	52.12	287,357	797.4	34,926.1
IWM	27.46	490,070	253.1	35,809.1
EFA	19.42	98,844	1178.4	78,870.3
EWZ	17.08	95,152	159.4	6,023.4
TLT	8.53	80,476	60.0	7,442.4
QQQ	26.25	579,404	351.6	50,359.7
EWJ	6.06	4,715	303.6	16,625.1
SPY	64.63	2,575,153	976.23	240,540.0

FINRA agrees as proposed by Cboe that the liquidity in the underlying ETFs, and the liquidity in the ETF options support its request to increase the position limits for the options subject to the proposed rule change. As to the underlying ETF shares, the average daily trading volume across all exchanges for the period of January 1 to July 31, 2017 was: (i) FXI–15.08 million shares; (ii) EEM–52.12 million shares; (iii) IWM–27.46 million shares; (iv) EFA–19.42 million shares; (v) EWZ–17.08 million shares; (vi) TLT–8.53 million shares; (vii) QQQ– 26.25 million shares; (vii) EWJ–6.06 million shares; and (viii) SPY–64.63 million shares.

In proposing the increased position limits, FINRA considered the availability of economically equivalent products and their respective position limits. For instance, some of the ETFs underlying options subject to this proposal are based on broad-based indices that underlie cash-settled options that are economically equivalent to the ETF options that are the subject of this proposal and have no position limits (NDX and SPX). Other ETFs are based on broad-based indexes that underlie cash-settled options with position limits reflecting notional values that are larger than the current position limits for ETF analogues (EEM and EFA). Where there was no approved index analogue, FINRA believes, based on the liquidity, breadth and depth of the underlying market, that the index referenced by the ETF would be considered a broad-based index (example FXI and EWJ).[22] FINRA believes that if certain position limits are appropriate for the options overlying the same index, or an analogue to the basket of securities that the ETF tracks, then those same economically equivalent position limits should be appropriate for the option overlying the ETF. In addition, the market capitalization of the underlying index or reference asset is large enough to absorb any price movements that may be caused by an oversized trade. Also, the issuer may look to the stocks comprising the analogous underlying index or reference asset when seeking to create additional ETF shares which are part of the creation/redemption process to address supply and demand or to mitigate the price movement of the price of the ETF.

For example, the PowerShares QQQ Trust or QQQ is an ETF that tracks the Nasdaq 100 Index or NDX, which is an index composed of 100 of the largest non-financial securities listed on the Nasdaq Stock Market LLC (''Nasdaq''). Options on NDX are currently subject to no position limits but share similar trading characteristics as QQQ. Based on QQQ's share price of $154.5422 and NDX's index level of 6,339.14, approximately 40 contracts of QQQ equals one contract of NDX. Assume that options on NDX are subject to the standard position limit of 25,000 contracts for broad-based index options under options exchange rules. Based on the above comparison of notional values, this would result in a position limit equivalent to 1,000,000 contracts for QQQ as NDX's analogue. However, options on NDX are not subject to position limits and has an average daily trading volume of 15,300 contracts. Options on QQQ are currently subject to a position limit of 900,000 contracts but has a much higher average daily trading volume of 579,404 contracts. Furthermore, NDX currently has a market capitalization of $17.2 trillion and QQQ has a market capitalization of

[12] *See https://www.ishares.com/us/products/239637/ishares-msci-emerging-markets-etf.*

[13] *See https://www.ishares.com/us/products/239710/ishares-russell-2000-etf.*

[14] *See https://www.ishares.com/us/products/239623/.*

[15] *See https://www.msci.com/eafe.*

[16] *See https://www.ishares.com/us/products/239612/ishares-msci-brazil-capped-etf.*

[17] *See https://www.ishares.com/us/products/239454/.*

[18] *See https://indexes.nasdaqomx.com/Index/Overview/NDX.*

[19] *See https://www.ishares.com/us/products/239665/EWJ.*

[20] *See https://us.spdrs.com/en/etf/spdr-sp-500-etf-SPY.*

[21] *See* note 8.

[22] FINRA Rule 2360(b)(3)(B) establishes position limits for index options by incorporating by reference the position limit established by the options exchange on which the option trades. Options exchanges establish rules for index options based on the characteristic of the underlying index. *See, e.g.,* Cboe Rule 24.4 and MIAX Rule 1804.

$50,359.7 million, and the component securities of NDX, in aggregate, have traded an average of 440 million shares per day in 2017, both market capitalizations being large enough to absorb any price movement caused by a large trade in the QQQ. The Commission has also approved no position limit for options on NDX, although it has a much lower daily trading volume than its analogue, the QQQ. Therefore, FINRA believes it is reasonable to increase the position limit for options on QQQ from 900,000 to 1,800,000 contracts.

The SPDR® S&P 500® ETF Trust or SPY seeks to provide investment results that, before expenses, correspond generally to the price and yield performance of the S&P 500® Index or SPX, which is an index composed of 500 large-cap U.S. companies. Options on the SPX have no position limits and share similar trading characteristics as SPY. Based on SPY's price of $263.15 and SPX's index level of 2640.87, approximately 10 contracts of SPY equals one contract of SPX.[23] Assume that options on SPX are subject to the standard position limit of 25,000 contracts for broad-based index options under options exchange rules. Based on the above comparison of notional values, this would result in a position limit equivalent to 250,000 contracts for options on SPY as SPX's analogue. However, options on SPX are not subject to position limits and has an average daily trading volume of 1,101,185 contracts.[24] Options on SPY were recently changed to a position limit of 1,800,000 contracts for standardized options, but is currently subject to a conventional option position limit of 900,000 contracts but has a much higher average daily trading volume of 2,575,153 contracts.[25] Furthermore, as of December 29, 2017, SPX had a market capitalization of $23.9 trillion and SPY has a market capitalization of $277.54 billion, large enough to absorb any price movement caused by a large trade in the SPY. The Commission has also approved no position limit for options on SPX, although it has a much lower daily trading volume than its analogue, the SPY, for which the exchanges recently changed the position limit to 1,800,000 contracts. Therefore, FINRA believes it is reasonable to increase the position limits for options on SPY from 900,000 to 1,800,000 contracts.

The iShares Russell 2000 ETF or IWM, is an ETF that also tracks the Russell 2000 index or RUT, which is an index composed of 2,000 small-cap domestic companies in the Russell 2000 index. Options on RUT are currently subject to no position limits but share similar trading characteristics as IWM. Based on IWM's share price of $144.77 and RUT's index level of 1,486.88, approximately 10 contracts of IWM equals one contract of RUT. Assume that options on RUT are subject to the standard position limit of 25,000 contracts for broad-based index options under options exchange rules. Based on the above comparison of notional values, this would result in a position limit equivalent to 250,000 contracts for options on IWM as RUT's analogue. However, options on RUT are not subject to position limits and has an average daily trading volume of 66,200 contracts. Options on IWM are currently subject to a position limit of 500,000 contracts but has a much higher average daily trading volume of 490,070 contracts. The Commission has approved no position limit for options on RUT, although it has a much lower average daily trading volume than its analogue, the IWM. Furthermore, RUT currently has a market capitalization of $2.4 trillion and IWM has a market capitalization of $35,809.1 million, and the component securities of RUT, in aggregate, have traded an average of 270 million shares per day in 2017, both large enough to absorb any price movement caused by a large trade in the IWM. Therefore, FINRA believes it is reasonable to increase the position limit for options on IWM from 500,000 to 1,000,000 contracts.

EEM tracks the performance of the MSCI Emerging Markets Index or MXEF, which is composed of approximately 800 component securities from emerging market countries from all over the world. Below makes the same notional value comparisons as made above. Based on EEM's share price of $47.06 and MXEF's index level of 1,136.45, approximately 24 contracts of EEM equals one contract of MXEF. Assume that options on MXEF are subject to the standard position limit of 25,000 contracts for broad-based index options under options exchange rules. Based on the above comparison of notional values, this would result in a position limit economically equivalent to 604,000 contracts for options on EEM as MXEF's analogue. However, MXEF has an average daily trading volume of 180 contracts. Options on EEM is currently subject to a position limit of 500,000 contracts but has a much higher average daily trading volume of 287,357 contracts. Furthermore, MXEF currently has a market capitalization of $5.18 trillion and EEM has a market capitalization of $34,926.1 million, and the component securities of MXEF, in aggregate, have traded an average of 33.6 billion shares per day in 2017, both large enough to absorb any price movement caused by a large trade in the EEM. Therefore, based on the comparison of average daily trading volume, FINRA believes it is reasonable to increase the position limit for options on EEM from 500,000 to 1,000,000 contracts.

EFA tracks the performance of the MSCI EAFE Index or MXEA, which has over 900 component securities designed to represent the performance of large and mid-cap securities across 21 developed markets, including countries in Europe, Australia and the Far East, excluding the U.S. and Canada. Below makes the same notional value comparison as made above. Based on EFA's share price of $69.16 and MXEA's index level of 1,986.15, approximately 29 contracts of EFA equals one contract of MXEA. Assume options on MXEA are subject to the standard position limit of 25,000 contracts for broad-based index options under options exchange rules. Based on the above comparison of notional values, this would result in a position limit economically equivalent to 721,000 contracts for EFA as MXEA's analogue. Furthermore, MXEA currently has a market capitalization of $18.7 trillion and EFA has a market capitalization of $78,870.3 million, and the component securities of MXEA, in aggregate, have traded an average of 4.6 billion shares per day in 2017, both large enough to absorb any price movement caused by a large trade in EFA. However, MXEA has an average daily trading volume of 270 contracts. Options on EFA is currently subject to a position limit of 250,000 contracts but has a much higher average daily trading volume of 98,844 contracts. Based on the above comparisons, FINRA believes it is reasonable to increase the position limit for options on EFA from 250,000 to 500,000 contracts.

FXI tracks the performance of the FTSE China 50 Index, which is composed of the 50 largest Chinese stocks. There is currently no index analogue for FXI approved for options trading. Options on FXI are currently subject to a position limit of 250,000 contracts but has a much higher average daily trading volume of 15.08 million shares. However, the FTSE China 50 Index currently has a market capitalization of $1.7 trillion and FXI has a market capitalization of $2,623.18 million, both large enough to absorb any price movement caused by a large trade

[23] As of March 29, 2018.

[24] As of July 31, 2017.

[25] *See* note 7.

in FXI. The components of the FTSE China 50 Index, in aggregate, have an average daily trading volume of 2.3 billion shares. Based on the above comparisons, FINRA believes it is reasonable to increase the position limit for options on FXI from 250,000 to 500,000 contracts.

EWZ tracks the performance of the MSCI Brazil 25/50 Index, which is composed of shares of large and mid-size companies in Brazil. There is currently no index analogue for EWZ approved for options trading. Options on EWZ are currently subject to a position limit of 250,000 contracts but the ETF has a much higher average daily trading volume of 17.08 million shares. However, the MSCI Brazil 25/50 Index currently has a market capitalization of $700 billion and EWZ has a market capitalization of $6,023.4 million, both large enough to absorb any price movement caused by a large trade in EWZ. The components of the MSCI Brazil 25/50 Index, in aggregate, have an average daily trading volume of 285 million shares. Based on the above comparisons, FINRA believes it is reasonable to increase the position limit for options on EWZ from 250,000 to 500,000 contracts.

TLT tracks the performance of the ICE U.S. Treasury 20+ Year Bond Index, which is composed of long-term U.S. Treasury bonds. There is currently no index analogue for TLT approved for options trading. However, the U.S. Treasury market is one of the largest and most liquid markets in the world, with over $14 trillion outstanding and turnover of approximately $500 billion per day. TLT currently has a market capitalization of $7,442.4 million, both large enough to absorb any price movement caused by a large trade in TLT. Therefore, any potential for manipulation will not increase solely due to the increase in position limits as set forth in this proposal. Based on the above comparisons, FINRA believes it is reasonable to increase the position limit for options on TLT from 250,000 to 500,000 contracts.

EWJ tracks the MSCI Japan Index, which tracks the performance of large and mid-sized companies in Japan. There is currently no index analogue for EWJ approved for options trading. However, the MSCI Japan Index has a market capitalization of $3.5 trillion and EWJ has a market capitalization of $16,625.1 million, and the component securities of the MSCI Japan Index, in aggregate, have traded an average of 1.1 billion shares per day in 2017, both large enough to absorb any price movement caused by a large trade in EWJ. Options on EWJ is currently subject to a position limit of 250,000 contracts and has an average daily trading volume of 6.6 million shares. Based on the above comparisons, FINRA believes it is reasonable to increase the position limit for options on EWJ from 250,000 to 500,000 contracts.

FINRA believes that increasing the position limits for the conventional options subject to the proposed rule change would lead to a more liquid and competitive market environment for these options, which will benefit customers interested in these products.

Surveillance and Reporting

Further, FINRA believes that the increased position limits provisions are appropriate in light of the existing surveillance procedures and reporting requirements at FINRA,[26] the options exchanges, and at the several clearing firms, which are capable of properly identifying unusual or illegal trading activity. These procedures use daily monitoring of market movements by automated surveillance techniques to identify unusual activity in both options and underlying stocks.[27]

In addition, large stock holdings must be disclosed to the Commission by way of Schedules 13D or 13G.[28] Options positions are part of any reportable positions and cannot legally be hidden. Moreover, the previously noted Rule 2360(b)(5) requirement that members must file reports with FINRA for any customer that held aggregate large long or short positions of any single class for the previous day will continue to serve as an important part of FINRA's surveillance efforts.

Finally, FINRA believes that the current financial requirements imposed by FINRA and by the Commission adequately address financial responsibility concerns that a member or its customer will maintain an inordinately large unhedged position in any option with a higher position limit. Current margin and risk-based haircut methodologies serve to limit the size of positions maintained by any one account by increasing the margin or capital that a member must maintain for a large position. Under Rule 4210(f)(8)(A), FINRA also may impose a higher margin requirement upon a member when FINRA determines a higher requirement is warranted. In addition, the Commission's net capital rule [29] imposes a capital charge on members to the extent of any margin deficiency resulting from the higher margin requirement.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so FINRA can implement the proposed rule change immediately.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[30] which requires, among other things, that FINRA rules must 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. FINRA believes that the proposed rule change promotes consistent regulation by harmonizing position limits with those of the other self-regulatory organizations. FINRA further believes that increasing the position limit on conventional options promotes consistent regulation by harmonizing the position limit with its standardized counterpart. In addition, FINRA believes the proposed rule change will be beneficial to large market makers and institutions (which generally have the greatest ability to provide liquidity and depth in products that may be subject to higher position limits as has been the case with recently approved increased position limits),[31] as well as retail traders and public customers, by providing them with a more effective trading and hedging vehicle. In addition, FINRA believes that the structure of the options subject to the proposed rule change and the considerable liquidity of the market for those options diminishes the opportunity to manipulate these products and disrupt the underlying market that a lower position limit may protect against.

Increased position limits for select actively traded options, such as those proposed herein, is not novel and has been previously approved by the Commission. For example, the Commission has previously approved a position limit of 1,800,000 contracts on options on SPY.[32] Additionally, the Commission has approved similar proposed rule changes by the options exchanges to increase position and exercise limits for options on highly

[26] *See* Rule 2360(b)(5) for the options reporting requirements.

[27] These procedures have been effective for the surveillance of options trading and will continue to be employed.

[28] 17 CFR 240.13d–1.

[29] 17 CFR 240.15c3–1.

[30] 15 U.S.C. 78*o*–3(b)(6).

[31] *See* note 8.

[32] *See* note 7.

liquid, actively-traded ETFs,[33] including a proposal to permanently eliminate the position and exercise limits for options overlaying the S&P 500 Index, S&P 100 Index, Dow Jones Industrial Average, and Nasdaq 100 Index.[34] In approving the permanent elimination of position and exercise limits, the Commission relied heavily upon surveillance capabilities, and the Commission expressed trust in the enhanced surveillance and reporting safeguards in order to detect and deter possible manipulative behavior, which might arise from eliminating position and exercise limits.[35] Furthermore, as described more fully above, options on other ETFs have the position limits proposed herein, but their trading volumes are significantly lower than the ETFs subject to the proposed rule change.

Furthermore, the proposed position limits would continue to address potential manipulative activity while allowing for potential hedging activity for appropriate economic purposes. The creation and redemption process for these ETFs also lessens the potential for manipulative activity. When an ETF company wants to create more ETF shares, it looks to an Authorized Participant, which is a market maker or other large financial institution, to acquire the securities the ETF is to hold. For instance, IWM is designed to track the performance of the Russell 2000 Index. The Authorized Participant will purchase all the Russell 2000 constituent securities in the exact same weight as the index, then deliver those shares to the ETF provider. In exchange, the ETF provider gives the Authorized Participant a block of equally valued ETF shares, on a one-for-one fair value basis. The price is based on the net asset value, not the market value at which the ETF is trading. The creation of new ETF units can be conducted all trading day and is not subject to position limits. This process can also work in reverse where the ETF company seeks to decrease the number of shares that are available to trade. The creation and redemption process, therefore, creates a direct link to the underlying components of the ETF, and serves to mitigate potential price impact of the ETF shares that might otherwise result from increased position limits.

The ETF creation and redemption process keeps ETF share prices trading in line with the ETF's underlying net asset value. Because an ETF trades like a stock, its price will fluctuate during the trading day, due to simple supply and demand. If demand to buy an ETF is high, for instance, the ETF's share price might rise above the value of its underlying securities. When this happens, an Authorized Participant can arbitrage this difference by buying the underlying shares that compose the ETF and then selling the ETF shares on the open market. This drives the ETF's share price back toward fair value. Likewise, if the ETF starts trading at a discount to the securities it holds, the Authorized Participant can buy shares of the ETF and redeem them for the underlying securities. Buying undervalued ETF shares drives the price of the ETF back toward fair value. This arbitrage process helps to keep an ETF's price in line with the value of its underlying portfolio.

Lastly, the Commission expressed the belief that removing position and exercise limits may bring additional depth and liquidity without increasing concerns regarding intermarket manipulation or disruption of the options or the underlying securities.[36] FINRA's existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior, which might arise from eliminating position and exercise limits.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Analysis

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts, including anticipated costs, benefits, and distributional and competitive effects transfers of wealth, relative to the current baseline, and the alternatives FINRA considered in assessing how to best meet its regulatory objectives.

Regulatory Objective

FINRA is proposing to amend Rule 2360 to harmonize FINRA's position limits for conventional options with the position limit for standardized options.[37]

Economic Baseline

Per FINRA Rule 2360(b)(30)(A)(iii) conventional equity options are subject to a basic position limit of 25,000 contracts or higher for conventional option contracts on securities that underlie exchange-traded options qualifying for a higher tier as determined by option exchange rules. The existing position limits for conventional options on ETFs are: 900,000 contracts for SPY or QQQ, 500,000 contracts for IWM or EEM, and 250,000 contracts for FXI, EFA, EWZ, TLT, or EWJ. Option exchanges have recently increased (or in the case of SPY decreased from the pilot program) position limit options on several ETFs such as SPY, IWM, QQQ, EEM, FXI, EFA, EWZ, TLT, and EWJ.

Economic Impact

Benefits

As noted above, the proposed rule change would amend Rule 2360 to harmonize FINRA's position limits for conventional options with the position limit for standardized options.[38] For investors that short conventional equity options or buy them long, there is likely to be a natural size for an executed order that minimizes fixed and variable transaction costs, including but not limited to the bid-ask spread, price impact, and transaction fees. If the existing position limits for conventional equity options on select ETFs constrains the order size such that fixed and variable transaction costs are higher than optimal, then investors may benefit if the new position limit is no less than the natural size. In such an event, the cost to hedge an ETF would decline, thereby making it less costly to manage downside risk.

In addition, if the existing position limits serve as a constraint, then an

[33] *See* Securities Exchange Act Release No. 68086 (October 23, 2012), 77 FR 65600 (October 29, 2012) (Order Approving File No. SR–CBOE–2012–66); Securities Exchange Act Release No. 68478 (December 19, 2012), 77 FR 76132 (December 26, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–BOX–2012–23); Securities Exchange Act Release No. 68398 (December 11, 2012), 77 FR 74700 (December 17, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–ISE–2012–93); Securities Exchange Act Release No. 68293 (November 27, 2012), 77 FR 71644 (December 3, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–Phlx–2012–132); Securities Exchange Act Release No. 68358 (December 5, 2012), 77 FR 73708 (December 11, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSE MKT–2012–71); Securities Exchange Act Release No. 68359 (December 5, 2012), 77 FR 73716 (December 11, 2012) (Notice of Filing and Immediate Effectiveness of File No. SR–NYSE Arca–2012–132) and Securities Exchange Act Release No. 69457 (April 25, 2013), 78 FR 25502 (May 1, 2013) (Notice of Filing and Immediate Effectiveness of File No. SR–MIAX–2013–17).

[34] *See* Securities Exchange Act Release No. 44994 (October 26, 2001), 66 FR 55722 (November 2, 2001) (Order Approving File No. SR–CBOE–2001–22) and Securities Exchange Act Release No. 52650 (October 21, 2005), 70 FR 62147 (October 28, 2005) (Order Approving File No. SR–CBOE–2005–41) (''NDX Approval'').

[35] *See* NDX Approval at 62149.

[36] *See* NDX Approval at 62149.

[37] *See* note 8.

[38] *See* note 8.

increase in the position limit for conventional options on select ETFs would permit investors to more easily find a counterparty. If the number of counterparties increases, then the cost of hedging should decline as the half-spread narrows, thereby making it less expensive to manage downside risk.

The extent of the constraint imposed by the current limit on conventional options is related to the ability of an investor to achieve similar economic exposure through other means. If there are other securities, such as an option on a closely related index, that exist and provide similar economic exposure less expensively, then the value of lessening the position limit on conventional options on ETFs is lower. Members may rely on information and data feeds from the Options Clearing Corporation to assist in their monitoring position limits. Because position limits on the standardized and conventional side have traditionally been consistent, members have relied on this feed for both standardized and conventional options. If the position limits between standardized and conventional options are conformed, then the cost from monitoring position limits should decline for member firms.

Cost

The proposed rule change may impose limited operational cost on member firms that trade conventional options on ETFs, as these same firms would need to revise position limits that are used in trading systems. However, the proposed rule change should not impose additional costs, because it is difficult to disrupt or manipulate the underlying market, create an incentive to disrupt or manipulate the underlying market for the purpose of profiting from the options position, or disrupt or manipulate the options market for conventional options on ETFs affected by this proposed rule. ETFs that underlie options subject to the proposed rule change are highly liquid, and are based on a broad set of highly liquid securities, which makes the market difficult to manipulate or disrupt. In fact, options on certain broad-based security indexes have no position limits. Furthermore, the creation and redemption process for these ETFs reduces the potential for disruptive or manipulative activity. New ETF units may be created at any time during the trading day and are not subject to position limits. Consequently, there is a direct link between the underlying components of the ETF and the ETF, which keeps ETF share prices trading in line with the ETF's underlying net asset value.

Alternatives

No further alternatives are under consideration.

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

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 after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act[39] and Rule 19b–4(f)(6)[40] thereunder.

FINRA has asked the Commission to waive the 30-day operative delay so that FINRA may immediately harmonize position limits with those of other self-regulatory organizations to ensure consistent regulation. For this reason, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[41]

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 to determine whether the proposed rule should be approved or disapproved.

[39] 15 U.S.C. 78s(b)(3)(A).

[40] 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 the 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. FINRA has satisfied this requirement.

[41] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–FINRA–2018–034 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–FINRA–2018–034. 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 filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2018–034, and should be submitted on or before October 11, 2018.

[42] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–20435 Filed 9–19–18; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15690 and #15691; ALASKA Disaster Number AK–00039]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of ALASKA

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of ALASKA (FEMA—4391—DR), dated 09/05/2018.

Incident: Flooding.

Incident Period: 05/11/2018 through 05/13/2018.

DATES: Issued on 09/05/2018.

Physical Loan Application Deadline Date: 11/05/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 06/05/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/05/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Matanuska-Susitna Borough.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 156906 and for economic injury is 156910.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–20407 Filed 9–19–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Audit and Financial Management Advisory Committee (AFMAC)

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time and agenda for the next meeting of the Audit and Financial Management Advisory Committee (AFMAC). The meeting will be open to the public.

DATES: The meeting will be held on Wednesday, October 31, 2018, starting at 2:00 p.m. until approximately 4:00 p.m. Eastern time.

ADDRESSES: The meeting will be held at the U.S. Small Business Administration, 409 3rd Street SW, Office of Performance Management and Chief Financial Officer Conference Room, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the AFMAC must contact Tim Gribben by fax or email, in order to be placed on the agenda. Tim Gribben, Chief Financial Officer, 409 3rd Street SW, 6th Floor, Washington, DC 20416, phone (202) 205–6449; fax: (202) 481–0546; email: *timothy.gribben@sba.gov.*

Additionally, if you need accommodations because of a disability or require additional information, please contact Donna Wood at (202) 619–1608; email *Donna.Wood@sba.gov*; SBA Office of Performance Management & Chief Financial Officer, 409 3rd Street SW, Washington, DC 20416. For more information, please visit *www.sba.gov/about-sba/sba-performance.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the AFMAC. The AFMAC is tasked with providing recommendation and advice regarding the Agency's financial management, including the financial reporting process, systems of internal controls, and audit process and process for monitoring compliance with relevant law and regulations.

The purpose of the meeting is to discuss the SBA's Financial Reporting, Audit Findings Remediation, Ongoing OIG Audits including the Information Technology Audit, FMFIA Assurance/A–123 Internal Control Program, Credit Modeling, Performance Management, Acquisition Division Update, Improper Payments and current initiatives.

Timothy Gribben,

Chief Financial Officer and Associate Administrator, Office of Performance Management and Chief Financial Officer.

[FR Doc. 2018–20493 Filed 9–19–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15688 and #15689; MINNESOTA Disaster Number MN–00063]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Minnesota

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Minnesota (FEMA–4390–DR), dated 09/05/2018.

Incident: Severe Storms, Tornadoes, Straight-line Winds, and Flooding.

Incident Period: 06/15/2018 through 07/11/2018.

DATES: Issued on 09/05/2018.

Physical Loan Application Deadline Date: 11/05/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 06/05/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 09/05/2018, Private Non-Profit organizations that provide essential

services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Aitkin, Beltrami, Blue Earth, Brown, Carlton, Cass, Clearwater, Cottonwood, Faribault, Itasca, Jackson, Koochiching, Lake, Lyon, Martin, Murray, Nicollet, Nobles, Pine, Pipestone, Polk, Redwood, Renville, Rock, St. Louis, Sibley, and Watonwan Counties, and the Leech Lake Band of Ojibwe, Red Lake Nation, and White Earth Nation

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 156886 and for economic injury is 156890.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–20406 Filed 9–19–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Audit and Financial Management Advisory Committee (AFMAC)

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory committee meeting

SUMMARY: The SBA is issuing this notice to announce the location, date, time and agenda for the next meeting of the Audit and Financial Management Advisory Committee (AFMAC). The meeting will be open to the public.

DATES: The meeting will be held on Friday, October 5, 2018, starting at 1:00 p.m. until approximately 3:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held at the U.S. Small Business Administration, 409 3rd Street SW, Office of Performance Management and Chief Financial Officer Conference Room, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the AFMAC must contact Tim Gribben by fax or email, in order to be placed on the agenda. Tim Gribben, Chief Financial Officer, 409 3rd Street SW, 6th Floor, Washington, DC 20416, phone (202) 205–6449; fax: (202) 481–0546; email: *timothy.gribben@sba.gov.*

Additionally, if you need accommodations because of a disability or require additional information, please contact Donna Wood at (202) 619–1608, email: *Donna.Wood@sba.gov*; SBA Office of Performance Management & Chief Financial Officer, 409 3rd Street SW, Washington, DC 20416. For more information, please visit *www.sba.gov/about-sba/sba-performance.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the AFMAC. The AFMAC is tasked with providing recommendation and advice regarding the Agency's financial management, including the financial reporting process, systems of internal controls, audit process and process for monitoring compliance with relevant law and regulations.

The purpose of the meeting is to discuss the SBA's Financial Reporting, Audit Findings Remediation, Ongoing OIG Audits including the Information Technology Audit, FMFIA Assurance/A–123 Internal Control Program, Credit Modeling, Performance Management, Acquisition Division Update, Improper Payments and current initiatives.

Timothy Gribben,

Chief Financial Officer and Associate Administrator, Office of Performance Management and Chief Financial Officer.

[FR Doc. 2018–20491 Filed 9–19–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

New Special Experimental Project (SEP–16) To Evaluate Proposals for Delegation of Certain Program-Wide FHWA Responsibilities to States

AGENCY: Federal Highway Administration (FHWA), U.S Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The FHWA is establishing a new Special Experimental Project (SEP–16) to test and evaluate the delegation of program-level responsibilities of the Federal-aid highway program (FAHP) to States, including the appropriate steps States should take to request to exercise delegated authority. The FHWA anticipates there is interest in State assumption of program-level actions for approval of design standards, noise policies, preventative maintenance programs, and real property acquisitions and disposals. The term ''program-level actions'' in this context means decisions that apply generally to projects in a State and broadly affect the implementation of the Federal-aid highway program in the State, but excludes Federal decisions relating to eligibility, obligation, reimbursement, authorization, and compliance.

DATES: This new SEP–16 project is being initiated on September 20, 2018.

FOR FURTHER INFORMATION CONTACT: For technical information: Cindi Ptak, Office of Innovative Program Delivery (HIN), (202) 366–8408; for legal information: Janet Myers, Office of the Chief Counsel (HCC), (202) 366–2019, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this notice may be downloaded from the **Federal Register**'s home page at: *http://www.archives.gov*; the Government Publishing Office's database at: *https://www.gpo.gov/fdsys/*; or the specific docket page at: *www.regulations.gov.*

Background

The Fixing America's Surface Transportation (FAST) Act (Pub. L. 114–94) builds on the authorities and requirements in earlier legislation to promote the transition from FHWA project-level ''full-oversight'' of the FAHP to a risk-based approach to FHWA oversight activities. The FHWA's use of a risk-based approach to stewardship and oversight is intended to optimize the successful delivery of projects and to ensure compliance with Federal requirements by focusing FHWA resources most efficiently and effectively.

Unless authorized by law, FHWA may not delegate or assign its decision-making responsibilities to a State department of transportation (State DOT). Section 106(c) of Title 23, United States Code (U.S.C.), authorizes States to assume project responsibilities for design, plans, specifications, estimates, contract awards, and inspections for

projects that receive funding under Title 23, U.S.C., and are on the National Highway System (NHS), including projects on the Interstate System. The States may assume these responsibilities unless FHWA, acting under a delegation of authority from the Secretary, determines that the assumption is not appropriate (23 U.S.C. 106(c)(1)). For non-NHS projects, States must assume such responsibilities (23 U.S.C. 106(c)(2)).

Section 1316(a) of the FAST Act directs the Secretary of Transportation to use the authority under 23 U.S.C. 106(c) to the maximum extent practicable to allow a State to assume the responsibilities described in 23 U.S.C. 106(c) on both a project-specific and a programmatic basis. Section 1316 of the FAST Act seeks to expand the use of the 23 U.S.C. 106(c) authority for State assumption of responsibilities. State assumption of certain responsibilities is part of the transition to risk-based oversight of the FAHP. To implement section 1316 of the FAST Act, FHWA published a **Federal Register** notice soliciting feedback from States and other stakeholders on additional project-level authorities to assume under Title 23.[1] The responses received indicated an interest in State assumption of program-level actions for approval of design standards, noise policies, preventative maintenance programs, and utility procedures, as well as some areas of real estate acquisition. Some responses requested authority in areas that FHWA has determined already are within the 23 U.S.C. 106(c) assumption authority.

The FHWA is initiating a new SEP–16 pursuant to authority granted to the Secretary in 23 U.S.C. 502(b) to evaluate potential effects of State assumption of program-level FAHP responsibilities that are not currently assumable. The experimental authority may be used to test deviations from Title 23 statutory, regulatory, or policy provisions, provided that the experimental features are consistent with the overall purpose and intent of the underlying statute, regulation, or policy being tested. Actions explicitly prohibited by statute cannot be the subject of a SEP–16 experiment. The experiment must be consistent with other Federal laws that apply to Title 23 funded activities. For example, the recording statute, 31 U.S.C. 1501, and the Antideficiency Act (31 U.S.C. 1341(a)(1)(A)), vest the responsibility to record obligations of the Federal Government with the Federal agency responsible for administering the Federal assistance program. The FHWA is establishing this SEP–16 to consider program-level authorities (as opposed to project-level actions) States may want to assume. The term ''program-level authority'' in this context means decisions that apply generally to projects in a State and broadly affect the Federal-aid system in the State, but excludes Federal decisions relating to eligibility, obligation, reimbursement, authorization, and compliance.

This SEP–16 is intended to allow States to propose the assumption of Title 23 program-level responsibilities provided they can demonstrate they have, or can reasonably put in place, the necessary laws, regulations, controls, and resources to take on the Federal role. Because States already have experience with project-level assumptions under 23 U.S.C. 106(c), FHWA anticipates initially receiving proposals for program-level authority affecting these types of areas.

This SEP–16 will allow FHWA to understand the implications of delegation of program-wide decisions in various program areas. The lessons learned from SEP–16 will aid FHWA in developing comprehensive policies and inform stakeholders if the delegation of specific program-level authorities, or other discretionary authorities established in Title 23, is appropriate.

To facilitate public access to SEP–16 information, all SEP–16 proposals, workplans, and reports will be posted on a public facing website.

Solicitation of Letters of Interest

This notice announces SEP–16 and requests Letters of Interest. Entities eligible to submit letters (''Applicants'') are State DOTs as defined in 23 U.S.C. 101. Letters of Interest, which should be submitted to the appropriate FHWA Division Office, initiate the application process described below. The Letter of Interest should include a high-level description of the Applicant's proposal, reasons for wanting to assume the program-level authority, and the anticipated resulting improvements to program delivery. Ideally, the Applicant will quantify the resulting improvements in terms of project time and/or cost savings. The Applicant should include enough detail to allow FHWA to determine how the proposal deviates from current law (including regulations) and practice, and how the actions covered by the proposal are addressed in current policy. The Letter of Interest should reference the Title 23 program and the specific legal authority(ies) being requested for delegation. Further, the Applicant should provide specific examples that demonstrate experience with project-level delegation in the affected program area(s), if applicable, as well as the level of collaboration conducted so far with relevant FHWA Division or Program Offices about the proposal.

Application Process

The application process is three-tiered with each step developing more specifics of the proposed program-level assumption(s) for FHWA consideration and feedback. The FHWA will evaluate each step to determine whether a proposal falls within the scope of section 502(b) and is appropriate for this experimental process before inviting and working with an Applicant to proceed to the next step for more detailed proposal development.

The first step in the application process is the Letter of Interest described above. The FHWA will acknowledge receipt of the Letter of Interest and provide an anticipated timeframe for initially evaluating the proposal and providing a formal response. After review of the proposal, FHWA will provide a formal response that will either request the Applicant to proceed with submitting a Concept Paper, or provide FHWA's explanation for not advancing the proposal.

If a Concept Paper is requested, the Applicant should submit to the appropriate FHWA Division Office a narrative further detailing the Applicant's proposal. This Concept Paper should not exceed 5 pages and be formatted single-spaced, using a standard 12-point font with 1-inch margins. Charts, tables, and other items may also be submitted as attachments to supplement the narrative and do not count toward the five-page limit. The Concept Paper should demonstrate that the State has the necessary laws, regulations, controls, and resources in place to assume the Federal role for the program-level responsibilities requested. If applicable, the Applicant may use experience with assumption of project-level authorities to demonstrate readiness to assume program-level responsibilities. If any necessary piece is missing, the Applicant should outline a plan and timeline anticipated to put pieces in place. In addition, the Concept Paper should detail supporting analysis for the anticipated program delivery improvements and consider a risk assessment of the expected impact the assumption of authority may have on the State's program—specifically on resources, processes, and stakeholders—and include measures the State would use to ensure the responsibilities are carried out in accordance with Federal requirements. The Concept Paper

[1] 81 FR 59715 (August 30, 2016).

should also summarize any preparation the Applicant may need to make if the experiment is approved and the time necessary for that preparation (*e.g.,* provide training for staff; make needed changes to procedures, organization charts, etc.). The FHWA will evaluate the Concept Paper, and either request the Applicant to proceed to the Detailed Proposal stage, or provide an explanation for not advancing the request.

Since the requirements for the Detailed Proposal will vary depending on the complexity of the proposed program assumption and the results of FHWA's evaluation of the Concept Paper, the appropriate FHWA Division will coordinate with the Applicant in preparing the Detailed Proposal. At a minimum, the Applicant's Detailed Proposal should: (1) Propose a duration for conducting the experiment, including a timeline for any transition activities; (2) identify key personnel and contacts with proposed roles and responsibilities; and (3) recommend an Evaluation Plan with reporting mechanisms, performance measures, goals, and other evaluation criteria, and frequency of reviews. To provide consistency among the SEP–16 experiments, FHWA will provide the Applicant certain performance measures and evaluation criteria common to all SEP–16 Evaluation Plans.

Should FHWA decide to proceed with the experiment, FHWA and the Applicant will enter into a memorandum of understanding and develop a workplan for the experiment.

Conclusion

The FHWA is committed to continuing its transition to a risk-based approach to stewardship and oversight of the FAHP. To this end, SEP–16 is designed to provide FHWA with a better understanding of the implications of allowing States to assume program-level authorities in various program areas. This notice announces the SEP–16 and identifies the process for States to apply to assume program-level responsibilities for the FAHP in their States.

(Authority: 23 U.S.C. 315 and 502).

Issued in Washington, DC, on September 11, 2018.

Brandye L. Hendrickson,

Deputy Administrator, Federal Highway Administration.

[FR Doc. 2018–20347 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0148]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel REBEL SOUL; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0148 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0148 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0148,
- 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel REBEL SOUL is:

—*Intended Commercial use of Vessel:* ''Charter sport fishing and cruising''
—*Geographic Region Including Base of Operations:* ''Florida'' (Base of Operations: Fort Lauderdale, FL)
—*Vessel Length and Type:* 65′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2018–0148 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0148 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20463 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0147]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ONE IRON; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0147 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0147 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0147, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ONE IRON is:

—*Intended Commercial Use of Vessel:* ''pleasure charters, day charters around the Miami Area''

—*Geographic Region Including Base of Operations:* ''Florida'' (Base of Operations: Miami, FL)

—*Vessel Length and Type:* 49′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2018–0147 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0147 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20462 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0149]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel RICHARD H. DANA; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0149 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0149 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0149, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel RICHARD H. DANA is:

—*Intended Commercial Use of Vessel:* ''Coastwise transportation of passengers between points in the United States, its territorial sea, or the EEZ. This includes carriage of passengers, including charter parties, entirely within our territorial waters.''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, CA)

—*Vessel Length and Type:* 35′ full keeled cutter rigged twin masted ketch sailboat

The complete application is available for review identified in the DOT docket as MARAD–2018–0149 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0149 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their

organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20464 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0146]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel GIOVANNINO; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD 2018–0146 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0146 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0146, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel GIOVANNINO is:

—*Intended Commercial Use of Vessel:* ''Term charters, week long all-inclusive yacht charters''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, North Carolina, South Carolina, Virginia, Delaware'' (Base of Operations: Nassau, Bahamas)

—*Vessel Length and Type:* 52′ power catamaran

The complete application is available for review identified in the DOT docket as MARAD–2018–0146 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0146 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20459 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0145]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel FIRST WAVE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0145 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0145 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0145, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel FIRST WAVE is:

—*Intended Commercial Use of Vessel:* ''sunset cruises, half day or full day sailing trips, catamaran charters. On rare occasions, we might do a short two or three-day cruise.''

—*Geographic Region Including Base of Operations:* ''Florida'' (Base of Operations: South Florida)

—*Vessel Length and Type:* 39′ Catamaran

The complete application is available for review identified in the DOT docket as MARAD–2018–0145 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0145 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20458 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0152]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel OCEAN SPIRIT; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0152 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0152 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0152, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel OCEAN SPIRIT is:

—*Intended Commercial Use of Vessel:* ''Charter-Sailing Lessons''
—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, CA)
—*Vessel Length and Type:* 36′ sailing catamaran

The complete application is available for review identified in the DOT docket as MARAD–2018–0152 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0152 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20461 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0151]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MISS BROOKE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no

more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before October 22, 2018.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0151 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0151 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0151, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MISS BROOKE is:

—*Intended Commercial Use of Vessel:* ''Sportfishing and sightseeing charter.''
—*Geographic Region Including Base of Operations:* ''Oregon'' (Base of Operations: Brookings, Oregon''
—*Vessel Length and Type:* 28′ Aluminum hull cabin boat

The complete application is available for review identified in the DOT docket as MARAD–2018–0151 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0151 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * *

Dated: September 17, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–20460 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Prosthetics and Special-Disabilities Programs; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Federal Advisory Committee on Prosthetics and Special-Disabilities Programs will be held on October 17, 2018, in Room 530 and on October 18, 2018, in Room 730 at VA Central Office, 810 Vermont Avenue NW, Washington, DC 20420. The meeting will convene at 8:30 a.m. on both days, and will adjourn at 4:30 p.m. on October 17 and at 12 noon on October 18. This meeting is open to the public.

The purpose of the Committee is to advise the Secretary of VA on VA's prosthetics programs designed to provide state-of-the-art prosthetics and the associated rehabilitation research, development, and evaluation of such technology. The Committee also provides advice to the Secretary to serve Veterans with spinal cord injuries, blindness or visual impairments, loss of extremities or loss of function, deafness or hearing impairment, and other serious incapacities in terms of daily life functions.

On October 17, the Committee will receive briefings on Ethics; Audiology and Speech Pathology Services; Blind Rehabilitation Service; Pain Management; Prosthetic and Sensory Aids Service; and the Comprehensive Addiction and Recovery Act (CARA). On October 18, the Committee members will receive briefings from National Veterans Sports Programs and Special Events; Recreation Therapy Service; and Rehabilitation Technology Update.

No time will be allocated for receiving oral presentations from the public; however, members of the public may direct questions or submit written statements for review by the Committee in advance of the meeting to Judy Schafer, Ph.D., Designated Federal Officer, Veterans Health Administration, Patient Care Services, Rehabilitation and Prosthetic Services (10P4R), VA, 810 Vermont Avenue NW, Washington, DC 20420, or by email at *Judy.Schafer@va.gov.* Because the meeting is being held in a Government building, a photo I.D. must be presented at the Guard's Desk as a part of the clearance process. Therefore, you should allow an additional 30 minutes before the meeting begins. Any member of the public wishing to attend the meeting should contact Dr. Schafer at (202) 461–7315.

Dated: September 17, 2018.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–20475 Filed 9–19–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 83 Thursday,

No. 183 September 20, 2018

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, et al.

Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494

[CMS–3346–P]

RIN 0938–AT23

Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This proposed rule would increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 19, 2018.

ADDRESSES: In commenting, please refer to file code CMS–3346–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3346–P, P.O. Box 8010, Baltimore, MD 21244–1810.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3346–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Alpha-Banu Wilson, (410) 786–8687. We have also included a subject matter expert under the ''Provisions of the Proposed Rule'' section for each provision set out in the proposed rule.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary and Background

A. Purpose

Over the past several years, we have revised the Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) to reduce the regulatory burden on providers and suppliers while preserving health and safety. We identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and States could use to improve or enhance patient health and safety. We also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for patients while reducing burden on providers and suppliers of care, and we identified non-regulatory changes to increase transparency and to become a better business partner. In addition, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) have reaffirmed their commitment to the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objectives were to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.

In accordance with these goals, we published three final rules that identified unnecessary, obsolete, or excessively burdensome regulations on health care providers, suppliers, and beneficiaries. These rules further increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care:

- ''Reform of Hospital and Critical Access Hospital Conditions of Participation'', published May 16, 2012 (77 FR 29034);
- ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'', published May 16, 2012 (77 FR 29002) and;
- ''Regulatory Provisions to Promote Program Efficiency, Transparency, and

Burden Reduction; Part II'', published May 12, 2014 (79 FR 27105).

This proposed rule is a continuation of our efforts to reduce regulatory burden and is in accordance with the January 30, 2017 Executive Order ''Reducing Regulation and Controlling Regulatory Costs'' (Executive Order 13771). We propose changes to the current requirements, CoPs, and Conditions for Coverage (CfCs) that will simplify and streamline the current regulations and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing providers to focus on providing high-quality healthcare to their patients. This proposed rule will also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain requirements for providers and suppliers and remove obsolete, duplicative, or unnecessary requirements. Ultimately, these proposals balance patient safety and quality, while also providing broad regulatory relief for providers and suppliers.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on Medicare and Medicaid participating providers and suppliers and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to Requests for Information (RFIs) that were included in the 2017 prospective payment regulations for most provider types. We refer readers to the public comments that were submitted in response to the RFI for the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-0001.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2018-0053-0002.*
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*
- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

B. Summary of Major Provisions

We propose to reduce regulatory burden on providers and suppliers by modifying, removing, or streamlining current regulations that we now believe are excessively burdensome. The proposals fall under three categories: (1) Proposals that simplify and streamline processes, (2) proposals that reduce the frequency of activities and revise timelines, and (3) proposals that are obsolete, duplicative, or that contain unnecessary requirements, as follows.

1. Proposals That Simplify and Streamline Processes

a. Discharge Planning in Religious Nonmedical Health Care Institutions (RNHCIs)

We have concluded that a more condensed and flexible process for discharge planning for RNHCIs would reduce burden and simplify the discharge process for patients. Specifically, we propose to revise the requirements at 42 CFR 403.736(a), requiring an evaluation, and § 403.736(b), requiring a discharge plan. Instead of specifying detailed discharge processes, we would simply require RNHCIs to assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no plan, and provide discharge instructions to the patient and the patient's caregiver as necessary when the patient is discharged home.

b. Ambulatory Surgical Center (ASC): Transfer Agreements With Hospitals

We propose to remove the requirements at 42 CFR 416.41(b)(3), ''Standard: Hospitalization.'' This would address the competition barriers that currently exist in some situations where hospitals providing outpatient surgical services refuse to sign written transfer agreements or grant admitting privileges to physicians performing surgery in an ambulatory surgical center (ASC). The Emergency Medical Treatment and Labor Act emergency response regulations would continue to address emergency transfer of a patient from an ASC to a nearby hospital.

c. ASC Requirements for Comprehensive Medical History and Physical Assessment

We propose to remove the current requirements at § 416.52(a) and replace them with requirements that defer, to a certain extent, to the ASC policy and operating physician's clinical judgment to ensure that patients receive the appropriate pre-surgical assessments tailored to the patient and the type of surgery being performed. We still would require the operating physician to document any pre-existing medical conditions and appropriate test results, in the medical record, which would have to be considered before, during and after surgery. In addition, we have retained the requirement that all pre-surgical assessments include documentation regarding any allergies to drugs and biologicals, and that the medical history and physical examination (H&P), if completed, be

placed in the patient's medical record prior to the surgical procedure.

d. Hospice Requirements for Medication Management

We have concluded that the requirements at 42 CFR 418.106(a)(1), related to having on the hospice staff, an individual with specialty knowledge of hospice medications, is no longer necessary for various reasons. Therefore, we propose to remove these requirements.

In addition, we propose to replace the requirement that hospices provide a copy of medication policies and procedures to patients, families and caregivers with a requirement that hospices provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative, and family. This information would be provided in a more user-friendly manner, as determined by each hospice. We believe this could improve patients' and caregivers' comprehension and maximize the effectiveness of the education effort.

e. Hospice Requirements: Orientation of Skilled Nursing Facility (SNF) and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICF/IID) Staff

We propose to move the requirements at § 418.112(f) to the ''Written agreement'' standard at new § 418.112(c)(10). Moving the requirement for facility staff orientation from a standalone requirement that places responsibility solely on hospices to the section of the rule related to the written agreement established between hospices and skilled nursing facilities (SNFs) and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) will allow both entities to negotiate the terms for assuring orientation of facility staff. This will give hospices more freedom to develop innovative approaches and avoid effort duplication with other hospices that are orienting the same facility staff.

f. Hospital Quality Assessment and Performance Improvement Program (QAPI Program)

We propose a new standard at 42 CFR 482.21(f), ''Unified and integrated QAPI program for multi-hospital systems.'' We would allow a hospital that was part of a hospital system consisting of multiple separately certified hospitals using a system governing body that was legally responsible for the conduct of two or more hospitals, the system governing body could elect to have a unified and integrated Quality Assessment and Performance Improvement (QAPI) program for all of its member hospitals after determining that such a decision was in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital within the system would have to demonstrate that: The unified and integrated QAPI program was established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and the unified and integrated QAPI program would establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, were given due consideration, and that the unified and integrated QAPI program would have mechanisms in place to ensure that issues localized to particular hospitals were duly considered and addressed.

g. Hospital Requirements for Comprehensive Medical History and Physical Examinations (§§ 482.22, 482.24, and 482.51)

We propose to allow hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals could utilize a pre-surgery/pre-procedure assessment for an outpatient, instead of a comprehensive medical history and physical examination (H&P). We believe that the burden on the hospital, the practitioner, and the patient could be greatly reduced by allowing this option. In order to exercise this option, a hospital would need to document the assessment in a patient's medical record. The hospital's policy would have to consider patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure; nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and applicable state and local health and safety laws.

h. Hospital Infection Control Program

We propose a new standard at § 482.42(c), ''Unified and integrated infection control program for multi-hospital systems.'' Like the proposed requirements for a unified and integrated QAPI program, the proposed standard for infection control would allow a hospital that is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital within the system must demonstrate that: The unified and integrated infection control program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; the unified and integrated infection control program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated infection control program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and a qualified individual (or individuals) has been designated at the hospital as responsible for communicating with the unified infection control program and for implementing and maintaining the policies and procedures governing infection control as directed by the unified infection control program.

i. Special Requirements for Psychiatric Hospitals

We propose at § 482.61(d) to clarify the scope of authority for non-physician practitioners or Doctor of Medicine Doctor of Osteopathic Medicine (MD/DOs) to document progress notes of patients receiving services in psychiatric hospitals.

j. Special Requirement for Transplant Centers and Definitions

We are proposing a nomenclature change at part 482 and the transplant center regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61. This change would update the terminology used in the regulations to conform to the terminology that is widely used and understood within the transplant community, thereby reducing provider confusion.

k. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers

We propose to remove the requirements at § 482.82 that require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. Transplant centers will still be required to comply with the CoPs at §§ 482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under § 482.80.

l. Special Procedures for Approval and Re-Approval of Organ Transplant Centers

We propose to remove the requirements at § 488.61(f) through (h) with respect to the re-approval process for transplant centers. This change corresponds to the proposed removal of the provisions § 482.82.

m. HHA Requirements for Verbal Notification of Patient Rights and Responsibilities

We propose to remove the requirements for verbal (meaning spoken) notification of patient rights to those patient rights elements for which the Social Security Act (the Act) requires such verbal notification. Specifically, we propose to only require verbal notice for those rights related to payments made by Medicare, Medicaid, and other federally funded programs, and potential patient financial liabilities.

n. Personnel Requirements for Portable X-Ray Technologists

We propose to revise § 486.104, ''Condition for coverage: Qualifications, orientation and health of technical personnel'', to align the current requirements at § 486.104(a)(1), (2), (3), (4) with § 482.26(c)(2), which refers to qualifications of radiologic technologists in hospitals and is focused on the qualifications of the individual performing services.

o. Portable X-Ray Requirements for Orders

We propose to revise the requirements for portable x-ray orders at § 486.106(a)(2). We propose to remove the requirement that physician or non-physician practitioner's orders for portable x-ray services must be written and signed. We also propose to replace the specific requirements related to the content of each portable x-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable x-ray services. These proposed changes would simplify the ordering process for portable x-rays and promote the use of more efficient ordering methods, such as electronic orders.

p. Emergency Preparedness Requirements: Requirements for Emergency Plans

We propose to eliminate part of the requirement from § 482.15(a)(4) for hospitals and other parallel provisions for other affected Medicare and Medicaid providers and suppliers (referred to collectively as ''facilities,'' throughout the remainder of this proposed rule where applicable), that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials, and that facilities document their participation in collaborative and cooperative planning efforts. In accordance with the remaining requirement at § 482.15(a)(4), facilities would still be required to include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. Only the documentation requirements would be eliminated.

2. Proposals That Reduce the Frequency of Activities and Revise Timelines

a. Home Health Agency (HHA) Requirements for Providing Patients With Copies of Clinical Records

We propose to remove the requirement that Home Health Agencies (HHAs) provide a copy of the clinical record to a patient, upon request, by the next home visit. We propose to retain the requirement that the copy of the clinical record must be provided, upon request, within 4 business days.

b. CAH Annual Review of Policies and Procedures

We propose to change the requirement at § 485.635(a)(4) to reflect the current medical practice where providers are expected to update their policies and procedures as needed in response to regulatory changes, changes in the standard of care, or nationally recognized guidelines. The current CoP at § 485.635(a)(4) requires a CAH's professional personnel to review its policies at least annually and the CAH to review as necessary. We propose to reduce burden and provide flexibility by requiring the CAH's, professional personnel, at a minimum, to conduct a biennial review of its policies and procedures instead of an annual review.

c. Comprehensive Outpatient Rehabilitation Facility (CORF) Utilization Review Plans

We propose to amend the utilization review plan requirements at § 485.66 to reduce the frequency of utilization reviews from quarterly to annually. This would allow an entire year to collect and analyze data to inform changes to the facility and the services provided.

d. Community Mental Health Center (CMHC) Requirements for Updating the Client Assessment

We propose to remove the requirement that all Community Mental Health Center (CMHC) clients receive an updated assessment every 30 days. Instead, we would require updates of the patient assessment in accordance with client needs and standards of practice. For clients receiving partial hospitalization services, we propose to retain the 30 day assessment update time frame in accordance with existing Medicare payment requirements for partial hospitalization services.

e. RHC and FQHC Review of Patient Care Policies

We propose to revise the requirement at § 491.9(b)(4) that RHC and FQHC patient care policies are reviewed at least annually by a group of professional personnel to review every other year to reduce the frequency of policy reviews.

f. RHC and FQHC Program Evaluation

We propose to revise the requirement at § 491.11(a) by changing the frequency of the required RHC or FQHC evaluation from annually to every other year.

g. Emergency Preparedness Requirements: Requirements for Annual Review of Emergency Program

On September 16, 2016, we finalized a rule imposing emergency preparedness requirements on most Medicare and Medicaid facilities (Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 FR 63860). Facilities participating in Medicare and/or Medicaid are now required, among other things, to review their emergency preparedness programs annually. This includes a review of their emergency plans, policies and procedures, communication plans, and training and testing programs. We propose to revise these requirements, so that applicable providers and suppliers have increased flexibility with compliance.

h. Emergency Preparedness Requirements: Requirements for Training

As with the review of the emergency plan previously discussed, we propose to revise the requirement that facilities develop and maintain a training program based on the facility's emergency plan annually. Instead, we would require that facilities provide training biennially (every 2 years) after facilities conduct initial training for their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated.

i. Emergency Preparedness Requirements: Requirements for Testing

For inpatient providers, we propose to expand the types of acceptable testing exercises that may be conducted such that one of the two annually required testing exercises may be an exercise of their choice, which may include one community-based full-scale exercise, if available, an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. For outpatient providers, we propose to revise the requirement such that only one testing exercise is required annually, which may be either one community-based full-scale exercise, if available, or an individual facility-based functional exercise, every other year and in the opposite years, these providers may chose the testing exercise of their choice which may include a community-based full-scale exercise, if available, a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

3. Proposals That Are Obsolete, Duplicative, or That Contain Unnecessary Requirements

a. Hospice Aide Training and Competency Requirements

We propose to revise § 418.76(a)(1)(iv) to remove the requirement that a State licensure program meet the specific training and competency requirements set forth in § 418.76(b) and (c) in order for such licensure to qualify a hospice aide to work at a Medicare-participating hospice. We would defer to State licensure requirements regardless of their content or format, and would allow states to set forth training and competency requirements that meet the needs of their populations. We believe that this change would streamline the hiring process for most hospices.

b. Medical Staff: Autopsies

We propose to remove the requirement for hospitals at § 482.22(d), which states that a hospital's medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. We propose to instead defer to State law regarding such medical-legal requirements.

c. Hospital and CAH Swing-Bed Requirements

We propose to remove the cross reference to § 483.10(f)(9) at § 482.58(b)(1) (for hospital swing-bed providers) and § 485.645(d)(1) (for CAH swing-bed providers). The cross-reference gives a resident the right to choose to, or refuse to, perform services for the facility if they so choose. If the resident works, the facility must document it in the resident's plan of care, noting whether the services are voluntary or paid, and, if paid, providing wages for the work being performed, at prevailing rates.

We propose to remove the cross-reference to § 483.24(c) at § 482.58(b)(4) (for hospital swing-bed providers) and § 485.645(d)(4) (for CAH swing-bed providers). This cross reference requires that the facility provide an ongoing activity program based on the resident's comprehensive assessment and care plan directed by a type of qualified professional specified in the regulation.

We propose to remove the cross-reference to § 483.70(p) at § 482.58(b)(5) (for hospital swing-bed providers) and § 485.645(d)(5) (for CAH swing-bed providers requiring facilities with more than 120 beds to employ a social worker on full-time basis).

We propose to remove the cross-reference to § 483.55(a)(1) at § 482.58(b)(8) (for hospital swing-bed providers) and § 485.645(d)(8) (for CAH swing-bed providers) requiring that the facility assist residents in obtaining routine and 24-hour emergency dental care.

d. Home Health Agency Home Health Aide Supervision Requirements

We propose to revise the requirement at § 418.76(h) related to completing a full competency evaluation when an aide is found to be deficient in one or more skills. Instead of completing a full competency evaluation, an aide would only be required to complete retraining and a competency evaluation directly related to the deficient skills.

e. CAH Disclosure Requirements

We propose to remove § 485.627(b)(1), the requirement for CAHs to disclose the names of people with a financial interest in the CAH. This is currently a requirement under the program integrity requirements at 42 CFR 420.206, which are referenced in the provider agreement rules in 42 CFR 489.53(a)(8). The provider agreement rules note that the basis for termination of the provider agreement includes failure of the provider to furnish ownership information as required in § 420.206, making this CAH CoP requirement duplicative of those regulations.

C. Summary of Costs and Benefits

1. Overall Impact

This proposed rule would create savings and reduce burden in many areas. Several of the proposed changes would create measurable monetary savings for providers and suppliers, while others would create less quantifiable savings of time and administrative burden. We estimate a total annual savings of $1,123 million using the midpoints of estimated ranges. We also estimate a one-time implementation cost of $64 million.

2. Section-by-Section Economic Impact Estimates

Table 1 summarizes the provisions for which we are able to provide specific estimates for savings or burden reductions (these estimates are uncertain and could be substantially higher or lower, as explained in the regulatory impact analysis section of this proposed rule):

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Provider or supplier type and description of proposed provisions	Frequency	Number of affected entities	Estimated annual savings or benefits ($millions)
Religious Nonmedical Health Care Institution:			
• Discharge Planning	As patients are discharged (Estimated 619 annual discharges).	18	(*)
Ambulatory Surgical Center:			
• Governing Body and Management	Upon failed hospital transfer agreement attempts.	5,557	(*)
• Patient Admission, Assessment and Discharge (History and Physical) **.	Every patient admission to an ASC or hospital outpatient.	[1] 5,557 [2] 5,031	454
• Medical Records	Recurring annually	5,557	0
Hospices:			
• Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.	Recurring annually	1,151	80
• Hospices That Provide Hospice Care to residents of a SNF/NF or ICF/IID.	Recurring annually	4,602	(*)
• Hospice Aide and Homemaker Services	Recurring annually	3,498	2
Hospitals:			
• Quality Assessment and Performance Improvement Program	Recurring annually	5,031	28
• Medical staff: Autopsies	Recurring annually	5,031	0
• Infection Control	Recurring annually	5,031	105
• Special requirements for hospital providers of long-term care services (“swing-beds”).	Recurring annually	5,031	30
• Special Requirements for Psychiatric Hospitals	Recurring annually	574	62
Transplant Programs:			
• Various provisions related to performance ***	Recurring annually	750	[3]
Home Health Agencies:			
• Patient rights	Recurring annually	12,624	55
• Home health aide services	Recurring annually	12,624	0
• Clinical records	Recurring annually	12,624	0
Critical Access Hospitals:			
• Provision of Services	Recurring biennially	1,343	2
• Organizational structure	Recurring annually	1,343	(*)
• Special requirements for hospital providers of long-term care services (“swing-beds”).	Recurring annually	1,246	86
Comprehensive Outpatient Rehabilitation Facilities:			
• Utilization Review Plan	Recurring annually	188	(*)
Community Mental Health Centers:			
• Assessment Update	Recurring annually	52	(*)
Portable X-Ray Services:			
• Qualifications of X-ray technicians ***	Annual	500	31
• Removing written orders	Annual	500	29
RHC (4,160 clinics) & FQHC (7,874 center locations):			
• Provision of Services	Recurring biennially	12,034	7
• Program Evaluation	Recurring biennially	12,034	9
Emergency Preparedness for Providers and Suppliers:			
• Annual Review of Emergency Preparedness Program	Recurring annually	72,844	94
• Emergency Plan	Recurring annually	68,254	7
• Training and Testing-Training Program	Recurring annually	69,196	33
• Training and Testing-Testing	Recurring annually	36,971	9
Total Annual Savings			1,123
Life-extending benefits for transplant patients **			[3]

* Amount is less than 1 million dollars.
** These include proposed changes to the following requirements: Special Requirements for Transplant Programs; Data submission, Clinical Experience, and Outcome Requirement for Re-approval of Transplant Programs; and Special Procedures for Approval and Re-Approval of Organ Transplant Programs.
*** This estimate is for first full year savings only and will increase in future years.
[1] (ACSs).
[2] (Hospitals).
[3] Not Quantified.

II. Provisions of the Proposed Regulations

A. Religious Nonmedical Health Care Institutions (RNHCIs)—Discharge Planning (§ 403.736(a) and (b))

Section 1861(ss)(1) of the Act defines the term ''Religious Nonmedical Health Care Institution'' (RNHCI) and lists the requirements that a RNHCI must meet to be eligible for Medicare participation. We have implemented these provisions in 42 CFR part 403, subpart G, ''Religious Nonmedical Health Care Institutions Benefits, Conditions of Participation, and Payment.'' Currently there are 18 Medicare-certified RNHCIs that are subject to the RNHCI regulations.

A RNHCI provides only non-medical items and services through non-medical nursing personnel on a 24-hour basis. These services are provided to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. ''Religious non-medical care'' or ''religious method of healing'' means care provided under established religious tenets that prohibit conventional or unconventional medical care for the treatment of the patient, and exclusive reliance on religious activity to fulfill a patient's total healthcare needs. The RNHCI does not furnish medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs or biologicals to its patients.

Section 403.736(a) and (b) of the RNHCI's CoPs, as amended in the November 28, 2003 **Federal Register** (68 FR 66710), requires RNHCIs to have a discharge planning process for patients. We reviewed the current CoPs and payment for RNHCIs at 42 CFR part 403, subpart G, in an effort to reduce burden and provide flexibility as feasible. As a result of the review, we identified discharge planning as one area where we could reduce burden. The current discharge planning requirements at § 403.736(a) and (b) require RNHCIs to have a discharge planning process that applies to all patients, and to assure that appropriate post-institution services are obtained for each patient, as necessary.

Currently, § 403.736(a)(1) requires RNHCIs to assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning and for any other patient upon his or her request or at the request of his or her legal representative. In accordance with § 403.736, this discharge planning evaluation must be initiated at admission and must include the following:

- An assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services.
- An assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.
- The staff must complete the assessment on a timely basis so that arrangements for post-RNHCI care are made before discharge and so that unnecessary delays in discharge are avoided.
- The discharge planning evaluation must be included in the patient's care record for use in establishing an appropriate discharge plan. Staff must discuss the results of the discharge planning evaluation with the patient or a legal representative acting on his or her behalf.
- If the discharge planning evaluation indicates a need for a discharge plan, qualified and experienced personnel must develop or supervise the development of the plan.
- In the absence of a finding by the RNHCI that the beneficiary needs a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.
- The RNHCI must arrange for the initial implementation of the beneficiary's discharge plan.
- If there are factors that may affect continuing care needs or the appropriateness of the discharge plan, the RNHCI must reevaluate the beneficiary's discharge plan. The RNHCI must inform the beneficiary or legal representative about the beneficiary's post-RNHCI care requirements.
- The discharge plan must inform the beneficiary or his or her legal representative about the freedom to choose among providers of care when a variety of providers is available that are willing to respect the discharge preferences of the beneficiary or legal representative.

Since the RNHCI's religious tenets prohibit conventional or unconventional medical treatment of a beneficiary, we believe that the extensive requirements previously discussed are unnecessarily burdensome, because medical post-institution services are not utilized by RNHCI patients.

Based on our experience with RNHCIs, patients are routinely discharged to home and not to an acute or post-acute care medical provider or supplier. We do not see a need for RNHCIs to develop a discharge plan that includes medical care once a patient leaves the RNHCI, because doing so is not in keeping with the religious tenets and goals of the facility. However, we believe that it is important to discuss with the caregiver at home about a safe and healing environment at home and to monitor the individual to access any changes in the patient's well-being and the need to seek additional care. We would expect RNHCIs to have policies and procedures that address their discharge processes. If the RNHCI determines that a patient either does or does not require discharge instructions, this decision must be made based on the RNHCI's existing policies. Surveyors would be expected to review the RNHCI policies and confirm that either the existence or lack of discharge instructions is consistent with policies established by the RNHCI.

We propose a more condensed and flexible process for discharge planning and instructions for RNHCIs. Specifically, we propose to remove the requirements at § 403.736(a) and (b), proposing instead to require RNHCIs to provide discharge instructions to the patient and/or the patient's caregiver when the patient is discharged home. We also propose that paragraphs (c) and (d) be redesignated as paragraphs (b) and (c).

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction for future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on RNHCIs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective.

We also note that such suggestions could include or expand upon comments submitted in response to the FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment

regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Mary Collins, (410) 786–3189.

B. Ambulatory Surgical Centers

Section 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. Currently, there are 5,591 Medicare certified ASCs in the United States.

Section 1832(a)(2)(F)(i) of the Act specifies that ASCs must meet health, safety, and other requirements specified by the Secretary in regulation in order to participate in Medicare. The Secretary of the Department of Health and Human Services (the Secretary) is responsible for ensuring that the CfCs protect the health and safety of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients.

The ASC regulations were first published on August 5, 1982 (47 FR 34082) and have since been amended several times. On November 18, 2008, we published a final rule, entitled ''Medicare Program: Changes to the Ambulatory Surgical Center Conditions for Coverage'', (73 FR 68502) revising four existing health and safety CfCs and created three new health and safety CfCs. In addition, several other small changes have been made in the past several years to amend the emergency equipment requirements (77 FR 29002) and radiologic services requirements required in the ASCs (79 FR 27106).

1. Governing Body and Management (§ 416.41(b)(3)(i) and (ii))

Hospitalization Requirements

Section 416.41(b) outlines the patient hospitalization procedures that ASCs must have in place to participate in Medicare. Section 416.41(b)(1) states the ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care that surpass the capabilities of the ASC. Additionally, there are two requirements that also pertain to ASC patient hospital transfers. Section 416.41(b)(3)(i) and (ii) requires ASCs to have a written transfer agreement with a hospital that meets certain Medicare requirements or ensure all physicians performing surgery in the ASC have admitting privileges in a hospital that meets certain Medicare requirements. A written transfer agreement and physician admitting privileges is intended to make sure there is a relationship between the ASC and local hospital that would serve the patient in the event of a medical emergency. Over the past 5 years, we have heard from the largest ASC trade association and multiple ASCs that we need to address the widespread issue of the growing number of hospitals that are declining to work with ASCs (either by declining to sign a transfer agreement or by declining to allow admitting privileges to the hospital by physicians who work in ASCs) due to competition between hospital outpatient surgery departments and ASCs. CMS has continually worked with the ASCs and hospitals directly to resolve this requirement issue, however, several facilities have not been able to reach a positive outcome. Furthermore, we have seen no evidence of negative patient outcomes due to a lack of such transfer agreements and admitting privileges. Research reports published by the ASC Quality Collaborative indicate the national hospital transfer rate from an ASC to a hospital for care is about 1.25 per 1,000 ASC admissions (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting/index.html*). ASCs are already required to have personnel trained and available for emergency response when there is a patient in the ASC. In addition, the ASC is expected to provide initial stabilizing treatment until the patient is transferred. Finally, the current requirement dates back to 1982, when ASCs were a newly emerging medical care option and there was reasonable concern as to needed emergency care being available.

EMTALA was enacted in 1986 and as its enforcement evolved over time this effectively has rendered such transfer agreements unnecessary, since EMTALA imposed requirements on all hospitals to provide emergency care without regard to prior arrangements until a patient could be stabilized and, as appropriate, either discharged because further care was not necessary, or transferred to another facility or care arrangement. Therefore, we conclude that these requirements are creating an administrative barrier to efficient ASC operations without any improvement in patient care or safety. In the absence of a transfer agreement or admitting privileges, ASCs would continue to have access to local emergency services to transfer patients to the nearest appropriate hospital for continued care. Hospitals are required to provide appropriate screening and stabilizing treatment for patients experiencing emergency medical conditions in accordance with the regulations set forth at § 489.24.

In light of these factors, we propose to remove the requirement for a written hospital transfer agreement or hospital physician admitting privileges at § 416.41(b)(3). We believe the proposed changes to the ASC hospitalization standard requirements would streamline ASC administrative operations and still assure the safety of these services while being less burdensome for Medicare-certified ASC facilities. The requirements in § 416.41(b)(1) and (2) continue to require the ASC to have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC and that the hospital must be a local hospital that meets the requirements for payment for emergency services under § 482.2. As part of this effective procedure, ASCs are not precluded from obtaining a hospital transfer agreements or hospital physician admitting privileges when possible. We would also like to solicit comments on burden that may result from the absence of a transfer agreement between ASCs and hospitals.

2. Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4))

The current regulations at § 416.52 require ASCs to ensure that a physician or other qualified practitioner provide a comprehensive medical history and physical assessment completed not more than 30 days before the date of the scheduled surgery. We have received feedback from stakeholders that the current requirement is overly burdensome for a large majority of healthy patients, specifically those patients who are receiving minimally invasive surgical procedures that are performed under minimal sedation or local anesthesia alone. For example, cataract surgery is the most commonly performed ASC surgical procedure among Medicare beneficiaries. Modern cataract surgery is a short procedure using mild sedation and local anesthesia. Medical complications for cataract surgery before, during and after surgery are extremely rare. Other ophthalmic procedures, such as Yttrium-Aluminum Garnet (YAG) laser capsulotomy, does not require a local

anesthetic and is a painless 60 second procedure that can be completed during a routine patient visit. However, when it is performed in an ASC, which enables one laser to be utilized by multiple surgeons for procedures, the requirement for a history and physical is burdensome to the patient and medical staff without any additional benefits. One study published in the New England Journal of Medicine concluded that routine preoperative medical testing (blood counts, clotting studies, chemistry panels, electrocardiograms, chest x-ray, etc.) conferred no measurable value in reducing adverse medical events on the day of surgery or up to one week postoperatively (Schein OD, Katz J, Bass EB, et al. Study of Medical Testing for Cataract Surgery. The value of routine preoperative medical testing before cataract surgery. New England Journal of Medicine. 2000; 342(3): 168–75). Another article on this issue from the Cochrane Database of Systematic Reviews reviewed three randomized clinical trials and also found that routine preoperative testing did not increase the safety of cataract surgery (Keay L, Lindsley K, Tielsch J, Katz J, and Schein O. Routine preoperative medical testing for cataract surgery, 2012;3:CD007293). These results are consistently found for other ambulatory surgeries. For example, one study tested over one thousand patients over a wide range of surgeries and found no increase in adverse events as a result of no preoperative testing (Chung F, Yuan H, Yin L, Vairavanathan S, and Wong DT. Elimination of preoperative testing in ambulatory surgery. Anaesth Analg. 2009 Feb: 108(s):467–75). Another and much larger study reviewed the literature on a broad range of ambulatory surgeries and examined records of results for over 73,000 patients who underwent various hernia surgeries and found that preoperative testing was not associated with rates of postoperative complications.

The vast majority of outpatient surgeries are performed on an outpatient or ''ambulatory'' basis precisely because they involve extremely low risk of complications due either to preexisting conditions or to the risk of the surgical procedure itself. Most such procedures are among those that are also routinely performed in physician offices. We further note that the specification of any short time period for the acceptability of pre-surgical evaluations (in other words, within 30 days) is inherently arbitrary and burdensome for the ASC patient population. For example, in the case of a cataract patient who needs a procedure in both eyes, a 31-day delay between the two operations would trigger the need for another physical examination and, possibly, another set of laboratory tests. Likewise, if an unanticipated event such as a death in the family required delaying a procedure by more than the 30th day after the examination, a duplicative examination and any necessary tests would be required. Moreover, if the examination and tests had been performed timely, but the results not transmitted in time, the duplicative examination and tests would be required.

We propose to remove the current requirements at § 416.52(a) and replace them with requirements that defer to the facility's established policies for pre-surgical medical histories and physical examinations (including any associated testing) and the operating physician's clinical judgment, to ensure patients receive the appropriate pre-surgical assessments that are tailored for the patient and the type of surgery being performed. We propose to require each ASC to establish and implement a policy that identifies patients who require an H&P prior to surgery. We propose that the policy would include the time frame for the H&P to be completed prior to surgery. ASCs may choose to continue the 30 day policy that has existed in regulation since 2008, or may choose a different time frame based on available evidence and standards of practice. We propose that the policy would be required to consider the age of patients, their diagnoses, the type and number of surgeries that are scheduled to be performed at one time, all known comorbidities, and the planned level of anesthesia for the surgery to be performed. ASCs would not be limited to these factors, and would be permitted to include others to meet the needs of their patient populations. Furthermore, we propose that each ASC's policy would be required to follow nationally recognized standards of practice and guidelines, as well as applicable state and local health and safety laws.

Particular subgroups of patients may benefit from more extensive and complete medical history and physical assessments prior to surgery. Those subgroups, for example, might include patients who cannot lie supine, have chest pain or shortness of breath, have pacemakers, have had a recent heart attack, on dialysis, or take insulin (Schein OD, Pronovost PJ. A Preoperative Medical History and Physical Should Not Be a Requirement for All Cataract Patients. DOI: 10.1007/s11606–017–4043–9, March 20, 2017.)

We would retain the requirement that the physician performing the surgery or other qualified practitioner perform a pre-surgical assessment for each ASC patient, including documentation regarding any allergies to drugs and biologicals. We would also retain the requirement that any documentation related to the H&P that may have been performed would be placed in the patient's medical record prior to the surgical procedure.

Our proposed change would simply eliminate the requirement for a pre-operative H&P, while allowing patient-specific physician decisions and ASC-wide policy decisions to determine what examinations and tests are necessary for each patient. Such decisions could be informed by specialty societies, medical literature, past experience, or other factors. We believe the proposed changes will reduce burden and provide flexibility for patients while maintaining a balance of health and safety requirements for providers.

In reading the discussion that follows, it is important to understand that the requirement for making a patient assessment at the ASC, on the day of surgery and before surgery commences, remains unchanged. This assessment addresses any new surgical risks for the patient with procedure-specific or patient-specific questions (for example, has the patient had a fever in the last 24 hours or, for a patient with diabetes, have there been any recent changes to random blood glucose levels with at-home monitoring?). The questions focus on any recent changes or updates to the patient's condition since the last H&P that might adversely impact the outcome of the procedure for the patient. This assessment must occur before proceeding with the procedure. Furthermore, we are not proposing to eliminate or discourage comprehensive pre-surgical H&Ps where warranted. To replace the current arbitrary 30-day rule applying to all patients, regardless of procedure or risk, we propose that each facility make an independent determination as to which procedures and which patient profiles would dictate requiring a pre-operative history and examination, taken before (but not necessarily 30 days before and possibly many months before) the day of surgery.

We request comment on whether we should make exceptions, such as for particular patient conditions or surgical procedures, that should not be entitled to such broad discretion, and for any evidence that would support such exceptions. We would also be interested in knowing if particular examinations or tests should be normal for those

conditions or procedures, and whether such standards would need be imposed by regulation or could rely on physician and facility judgment and practices.

3. Medical Records (§ 416.47)

The current regulations at § 416.47 require ASCs to maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. Section 416.47(b) sets out the form and content of the record, including specific items that must be included in the medical record. To conform to the proposed changes to the medical history and physical examination requirements at § 416.52(a), we propose to revise the requirement at § 416.47(b)(2) that states ''Significant medical history and results of physical examination'', by adding ''as applicable.'' This proposed revision would reflect the fact that, in accordance with our proposed changes to § 416.52(a), not all ASC patients may have a medical history and physical examination report that would be included in the medical record.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on ASCs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 OPPS/ASC proposed rule. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0091.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Jacqueline Leach, USPHS, 410–786–4282.

C. Hospice

1. Hospice Aide and Homemaker Services (§ 418.76)

Under the current hospice CoP requirements at § 418.76, all hospice aides are required to meet specific, federally-established, training and education requirements. The requirements are based on the training and education requirements for home health aides as set forth at section 1891(a)(3)(D) and 1861(m)(4) of the Act. Specifically, the current CoPs (§ 418.76(a)) require that a hospice aide must be a person who has completed one of the following: A training program and competency evaluation as specified in the regulations; a competency evaluation program that meets the requirements specified in the regulation; a nurse aide training and competency evaluation program in accordance with the requirements set forth in the long term care requirements; or a State licensure program that meets the requirements at § 418.76(b) (training) and (c) (competency evaluation). At § 418.76(b) and (c) of the hospice CoPs, we specifically detail the content and format of aide education, training, and of competency evaluations, including the number of classroom and practical training hours that must be completed, the skills that must be addressed, and the general method (exam or practical observation) used for assessing competency in those various skills.

We initially proposed and finalized these requirements in order to be consistent with the requirements that apply to home health aides (§ 484.80). Historically, a significant number of hospice agencies were HHA-based, meaning that the same entity provides both hospice and home health care services, often utilizing the same pool of staff to furnish both services. Using similar requirements for both hospices and home health agencies streamlines operations for hospices that are home health agency based. Due to the evolution of the hospice industry as a whole, the proportion of HHA-based hospices has significantly declined, reducing the streamlining benefits that occur by having the same requirements for aides in both hospice and home health settings.

As the streamlining benefits for the hospice industry as a whole have reduced, the burden/benefit ratio related to meeting the prescriptive home health aide qualification requirements, which are required to be set forth in regulation by section 1891(a) of the Act, has shifted. While section 1891(a) of the Act requires CMS to establish prescriptive requirements for aides who provide services on behalf of home health agencies, the Act does not establish similarly prescriptive requirements for aides who provide services on behalf of hospices. In addition to the hospice aide qualifications that are established in the hospice CoPs, hospice aides must also be licensed, certified, or registered by the State in which they are practicing (if available), in accordance with the requirements at § 418.116(a). A hospice industry association conducted an informal survey of all 50 states and found that 76 percent of those states currently have their own hospice aide qualifications for licensure, certification, or registration. Therefore, we assume that in 76 percent of states, hospice aides are required to meet two different qualification standards (one for state licensure, certification, or registration; and one for compliance with the Federal CoPs).

This regulatory approach has created unintentional burden during the hiring process for all of the non HHA-based hospices, as well as those HHA-based hospices that do not share staff with the home health agency portion of their organization. The unintentional burden is the result of hospices having to verify during the aide hiring process that the applicant meets both the state licensure, certification, or registration requirements, and also meets the specific training and competency requirements set forth in the CoPs. State requirements may change at any time and hospices may receive employment applications from aides that have been trained in another setting such as nurse aide training in the long term care environment or private duty aide training not subject to Federal regulations, so hospices are burdened with the need to review, in detail, each employment applicant's training and competency content and format each time they need to make a new hire. For example, State requirements may specify a different number of training hours to be completed, a different format for assessing competency in a specific skill, or even a different set of mandatory skills in accordance with State scope of practice requirements. We believe that this is an unnecessary and inefficient use of hospice staff time that does not serve to improve patient care and safety.

To address these concerns, we propose to revise § 418.76(a)(1)(iv) to remove the requirement that a State licensure program must meet the specific training and competency requirements set forth in § 418.76(b) and

(c) in order to be deemed an appropriate qualification for employment. This change would defer to State licensure requirements, except in states where no requirements exist, regardless of their content or format, and would allow states to set forth training and competency requirements that meet the needs of their populations. We do not believe that it is necessary for the Federal government to oversee the qualifications established by states because these states have already demonstrated their willingness and ability to regulate this area along with federally established requirements. This change would also streamline the hiring process for most hospices. We would continue to require that hospice aides may only perform those skills that are consistent with the training that the aide has received (§ 418.76(g)(2)(iv)), and would continue to require that, if an area of concern is verified by the hospice during an on-site aide supervision visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation in accordance with § 418.76(c) and (h)(1)(iii). We believe that these requirements will ensure that aides only perform duties for which they are trained and that they perform such duties in a safe and effective manner. Furthermore, we would continue to require that hospices must comprehensively assess patients on a regular schedule and on an as needed basis (§ 418.54(a), (b) and (d)), assure that each patient's plan of care is developed and continually updated to meet each patient's needs as identified in the assessment process (§ 418.56(b) through (d)), assure that the plan of care reflects patient and family goals (§ 418.56(b) and includes all services (including aide services) necessary to manage pain and symptoms (§ 418.56(c)), and ensure that hospice care and services are provided in accordance with the plan of care and are based on all assessments of the patient and family needs (§ 418.56(e)). Furthermore, hospices would continue to be required to provide hospice care that optimizes comfort and dignity, and is consistent with patient and family needs and goals (§ 418.100(a)). Finally, hospices would continue to be required to maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program that involves all hospice services, including aide services, that focuses on indicators related to improved patient outcomes, and takes actions to demonstrate improvement in hospice performance (§ 418.58). While deferring to state requirements for hospice aide qualifications would likely introduce a new level of variability in the aide hiring process, we believe that the remaining hospice CoPs would continue to assure that hospice aide services meet the needs of patients and families, and are delivered in a safe and effective manner.

2. Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106(a)(1) and (e)(2)(i))

The June 5, 2008 Hospice CoP final rule (73 FR 32088) required hospices to ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs (§ 418.106(a)(1)). This requirement was implemented as a direct result of public comments that were submitted in regards to the May 2005 Hospice CoP proposed rule (70 FR 30840). The May 2005 Hospice CoP proposed rule proposed to retain longstanding requirements for pharmacist involvement in the planning and delivery of drugs and biologicals for patients that receive care in the hospice inpatient setting. Commenters suggested that we broaden our proposal and apply it to patients receiving care in all settings. The commenters stated that, since drugs are prescribed to virtually all hospice patients, these patients should benefit from the expertise of a pharmacist and the additional level of drug oversight required by the regulatory standards. We agreed with the commenters that it would be beneficial to patients to broaden the scope of the pharmacy requirements. For this reason, we finalized a requirement at paragraph (a), ''Managing drugs and biologicals,'' to require that each hospice ensures that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. Hospices have the option of using a licensed pharmacist or an individual who has an extensive and up-to-date knowledge of drugs, to fulfill this role.

At the time when this requirement was finalized in 2008, we estimated that 1,600 hospices (56 percent of all hospices) were already contracting with pharmacy benefit management companies to provide drugs and pharmacist services to each of their patients at a single bundled service rate. These hospices were already realizing the benefits of specialized drug management expertise in the absence of Federal regulations. Since 2008, the use of pharmacy benefit management companies, including their built-in pharmacy experts, has continued to grow at a rapid pace. Although there have been no formal studies on the proliferation of pharmacy benefit management company use in hospice, conversations with industry experts lead us to estimate that, at minimum, 75 percent of existing hospices use such services. Experts estimate that the more likely number is between 90 and 95 percent of hospices due to various factors that hospices find to be desirable, such as predictable capitated medication fees and direct to the patient door medication delivery services. Since the use of pharmacology experts has become routine due to the proliferation of pharmacy benefit management companies that provide pharmacist services for each patient bundled with drug and biologics supply services, we believe that it is no longer necessary to include a regulatory requirement specifically related to the use of a pharmacology expert. As pharmacy benefit management services bundle drug and biologics supply services with expert advice, and since industry experts estimate that at least 75 percent and as many as 95 percent of hospices use pharmacy benefit management services for reasons primarily unrelated to this specific regulatory requirement, we conclude that the vast majority of hospices, and thus the vast majority of hospice patients, will continue to receive such advice and guidance in the absence of regulation. This proposed change would allow hospices to more seamlessly integrate the information provided by the drug management expert into routine interdisciplinary group meetings rather than having to use burdensome formulaic approaches that hospices currently implement in order to demonstrate compliance with the regulation.

In addition to changes in the pharmacy benefit management landscape, there have also been significant changes in the hospice and palliative care nursing and physician landscapes. Since publication of the 2008 Hospice CoP final rule (73 FR 32088), the number of hospice and palliative care nursing and physician specialty training and certification programs has rapidly expanded. As more hospice and palliative care

nursing and physician specialists have entered the job market, more hospices are employing these clinicians with advanced skill sets. In hospices that do not use a pharmacy benefit management service, these clinicians typically fill the role of the required individual with education and training in drug management in addition to being the regular physician or nurse member of the interdisciplinary group. As these clinicians are already members of the core interdisciplinary group in accordance with the requirements at § 418.56(a), we believe that hospices will continue to benefit from their expertise in the absence of Federal regulations. For these reasons, we conclude that the requirements at § 418.106(a)(1) are no longer necessary to assure patient safety and the effectiveness of hospice care. Furthermore, we believe that hospices may achieve a cost savings upon removal of this requirement because they will no longer need to assure a dedicated time in each interdisciplinary group meeting in order to be able to document that a specific conversation occurred among group members, and thus document compliance with the regulation. Therefore, we propose to delete the requirements at § 418.106(a)(1).

Hospices would continue to be required to comprehensively assess patients on a regular schedule and on an as needed basis (§ 418.54(a), (b) and (d)), and to assure that each patient's plan of care is developed and continually updated to meet each patient's needs as identified in the assessment process (§ 418.56(b) through (d)). To the extent that a hospice needs additional expert information or expertise beyond what is provided by hospice employees and the pharmacy expertise of any pharmacy benefit manager that a hospice may choose to use in order to meet a given patient's assessment, care planning, and care delivery medication-related needs, we would continue to require that it secure such information and expertise. Meeting each patient's needs would continue to be the responsibility of all Medicare-participating hospices in accordance with the requirements of all other hospice CoPs.

The 2008 Hospice CoP final rule (73 FR 32088) also required hospices, at § 418.106(e)(2)), to: (1) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family; (2) discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and (3) document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed. We believe that the hospice, as well as the patient, family, and caregivers share the responsibility and accountability for maintaining controlled substances in the home. We believe that hospices must assume responsibility to educate the patient and family about the proper use and disposal of controlled drugs and biologicals that are maintained in the home environment. The drug policies and procedures also help the hospice explain its own role in controlled drug management.

We believe that this requirement continues to be relevant, particularly in relationship to implementing proper storage and security precautions that can prevent theft and other drug diversion in the home, and proper disposal when a drug is no longer needed to prevent inappropriate access and environmental damage. Therefore, we continue to expect that hospices would have such policies and procedures for their own internal use as part of routine business practice. However, hospice policies and procedures are typically written in ways that are not easily understood by the general public. Hospice clinicians spend more time than expected explaining technical terms and otherwise translating the policies and procedures into layperson's terms. We do not believe that this process of explaining complex documents in a manner that is meaningful to patients and families is beneficial to patients, families, caregivers, or hospices.

We propose to replace the requirement that hospices provide a physical paper copy of policies and procedures, which are written to guide the actions of hospice staff, with a requirement that hospices provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative, and family, which can be developed in a manner that speaks to the perspectives and information needs of patients and families. This information would be provided in a more user-friendly manner, as decided by each hospice, which we believe can improve comprehension and maximize the effectiveness of the education effort. Furthermore, by providing information in a more user-friendly manner, hospices would be able to eliminate time spent explaining technical terms and other otherwise translating the policies and procedures into layperson's terms. This would create more efficiency while simultaneously improving hospice-patient communications. Hospices would be free to choose the content and format(s) that best suits their needs and the needs of their patient population. We propose to require that, regardless of the format chosen, this information must be provided to patients and families in a manner that allows for continual access to the information on an as-needed basis in order to assure that patients and families have information available when they need it. CMS is soliciting input concerning what a standardized educational format should entail, including whether the format should be paper or electronic; in writing, pictorial, video, or audio; what general subjects should be addressed in regards to storage, disposal, use, and risks; and what specific content should be included to minimize opioid diversion and maximize safety.

We would continue to require that hospices discuss the information regarding the safe use, storage and disposal of controlled drugs with the patient or representative, and the family, in a language and manner that they understand to ensure that these parties are effectively educated. This requirement is included in the current hospice CoPs and is consistent with Department of Health and Human Services guidance regarding Title VI of the Civil Rights Act (''Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' 68 FR 47311, August 8, 2003, *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-Federal-financial-assistance-recipients-title-VI/*). We continue to expect hospices to utilize technology, such as telephonic interpreting services and any other available resources for oral communication in the individual's primary or preferred language. We would also continue to require that hospices document in the patient's clinical record that the information was provided and discussed.

3. Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/IID (§ 418.112 (c)(10) and (f))

Section 418.112(f) of the hospice CoPs, as finalized in the 2008 Hospice CoP final rule (73 FR 32088), requires hospices to assure orientation of Skilled Nursing Facility/Nursing Facility (SNF/NF) or ICF/IID staff furnishing care to

hospice patients. This orientation is required to include information concerning the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements. The intent of this standard is to ensure that facility staff who furnish care to residents who are hospice patients are provided information on the hospice philosophy and approach to care, much in the same way that home caregivers are routinely provided information on the hospice philosophy and approach to care. It is the hospice's responsibility to coordinate the trainings with representatives of the facility. It is also the hospice's responsibility to determine how frequently training needs to be offered in order to ensure that the staff furnishing care to hospice patients are oriented to the philosophy of hospice care.

We believe that the intent of the requirement to educate facility staff about hospice care continues to be an appropriate regulatory requirement. However, we believe that, as currently written and implemented, this requirement may create duplication when multiple hospices provide care to the residents of a single facility. Furthermore, by assigning sole responsibility for this effort to hospice providers, this requirement may impede joint hospice-facility collaboration and training innovations. Creating duplicative efforts and impeding collaboration may increase hospice burden without improving the care of hospice patients. Therefore, we believe that it is appropriate to revise the current requirement.

Specifically, we propose to remove § 418.112(f) and add a new requirement at § 418.112(c)(10), ''Written agreement,'' to address this issue. Moving the requirement for facility staff orientation to the standard related to the written agreement established between hospices and facilities would ensure that both entities negotiate the mechanism and schedule for assuring orientation of facility staff. Additionally, enabling hospices and facilities to negotiate their now shared role would encourage collaboration between both entities, avoid duplication of efforts with other hospices that are orienting the same facility staff, and provide incentives to facilities to become more engaged in the hospice orientation process for facility staff.

We are seeking public comment on all of the proposed hospice changes. In addition, we note that we seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on hospices and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/document?D=CMS-2017-0062-0001.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Danielle Shearer, 410–786–6617.

D. Hospitals

1. Quality Assessment and Performance Improvement Program (§ 482.21)

On May 16, 2012, we published a final rule, entitled ''Reform of Hospital and Critical Access Hospital Conditions of Participation'' (77 FR 29034). In that rule, we finalized changes to the requirements of the ''Governing body'' CoP, § 482.12, and adopted a policy to allow one governing body to oversee multiple hospitals in a multi-hospital system. We noted in this rule that the regulations, as finalized, were intended to provide systems that own two or more hospitals with an option, but not a requirement, to use a system governing body for two or more hospitals. In those instances where a system believes that its interests are best served by using a system governing body legally responsible for two or more hospitals, under the CMS regulations, that system will have the flexibility to do so, just as system that owns two or more hospitals will have the flexibility to continue with the model of a separate governing body for each hospital in its system if it determines that course would best serve its interests.

After publication of the May 2012 final rule, we received a considerable amount of feedback regarding our responses in the rule (77 FR 29061) where we discussed our interpretation of the Medical staff CoP at § 482.22 as requiring that each hospital have its own independent medical staff despite the arguable ambiguity of the regulatory language. It was brought to our attention that, over the years, this apparently ambiguous language might have led some stakeholders to interpret § 482.22 as allowing for separately certified hospitals, as members of a multi-hospital system, to share a unified and integrated medical staff. This eventually led to us proposing a requirement in a February 7, 2013 proposed rule, entitled ''Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction—Part II'' (78 FR 9216), which proposed to prohibit the use of a unified and integrated medical staff subject to a system governing body.

In the May 12, 2014 final rule, Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (79 FR 27105) that followed, and after carefully considering all of the arguments for and against allowing a system that owns two or more hospitals to use a unified and integrated medical staff structure for its member hospitals that are subject to a common system governing body, we came to the conclusion that it was in the best interest of hospitals, medical staff members, and patients for us to modify the proposed prohibition on the use of a unified and integrated medical staff for a multi-hospital system and its member hospitals so as to enable the medical staff of each hospital that is subject to a common system governing body to voluntarily integrate itself into a larger system medical staff.

The fact that many hospital systems had been using a unified medical staff model for a number of years, without evidence showing that such a model was detrimental to patients or decreased the quality of care delivered, was a major factor in our decision to allow hospitals and their respective medical staffs the flexibility to decide which medical staff framework worked best for

their particular situations. We received a large number of comments from individual physicians as well as national and State physician organizations that supported our proposed changes to reaffirm and make more explicit the requirement that each hospital to have its own medical staff, specifically those hospitals that are part of a multi-hospital system. These commenters stated they believe that allowing a multi-hospital system to have a unified and integrated medical staff instead of separate medical staffs for each hospital would destroy the concept of medical staff self-governance that is ''a basic requirement'' for TJC hospital accreditation and which is ''mandated by some states.'' Additionally, there were some comments from individuals as well as hospital leaders that stated that while they support the proposed requirement overall, they believe that there should be some allowance for hospitals within a system to share medical staff bylaws, rules, and regulations.

However, these arguments against allowing this flexibility through the CoPs did not provide any evidence that having a single and separate medical staff for each hospital within a system was inherently superior, particularly in the areas of patient safety and quality of care, to the unified and integrated medical staff model for two or more hospitals subject to a system governing body. We weighed this argument against the comments from the physician leaders and members of unified and integrated medical staffs who provided testimony and anecdotal evidence for the benefits of this type of structure. Additionally, we considered preliminary evidence that appeared to show that hospitals using a unified medical staff might be achieving some success in reducing Hospital-Acquired Conditions (HACs), Healthcare-Associated Infections (HAIs), and readmissions, and in improving patient safety and outcomes. During our preliminary development of this rule, we carefully considered any additional areas where we could provide further flexibility and reduce regulatory burden for hospitals. We were particularly interested in those areas that we had not considered or proposed in the previous rulemaking efforts discussed. As we noted with regard to the use of a unified medical staff model under a system governing body, much of the evidence and testimony provided to us at that time focused on observed improvements in patient safety, quality of care, and overall patient outcomes. In the May 2014 final rule previously referenced, one public commenter, writing on behalf of a multi-hospital system that the commenter references as the largest in their State, stated that ''we believe the concept of a single medical staff has substantially contributed to our success as an integrated delivery system and has accelerated our quality, safety and efficiency performance.'' The commenter also cited the system's achievements, which the commenter stated that they believe were a result of this single and integrated medical staff model: Core measures in the top quartile with excellent value-based purchasing scores according to CMS; lower in-hospital mortality rates that are statistically significant, that is, 17 percent lower than expected; lower hospital readmission rates that are statistically significant, that is, 15 percent lower than expected; and the second lowest congestive heart failure readmission rate in the nation, according to published CMS data.

Since those rules were published, we have not received any negative feedback on the regulatory changes or any evidence that the use of a unified medical staff model is detrimental to patients and their care. And because the potential benefits to using such a system appear to point to patient safety and quality of care specifically, we began to look at two areas in the CoPs for possible revision along these lines, two areas that we believe have the most direct impact on ensuring and promoting a culture of safety in hospitals—QAPI and infection control. We believe that applying the unified model to a hospital's QAPI program and/or a hospital's infection control program would be a natural progression for a multi-hospital system currently using a system governing body and a unified medical staff. By allowing a system governing body the option of unifying and integrating its various member hospital QAPI programs and/or infection control programs into unified programs incorporating each individual hospital's QAPI program and/or infection control program (and thus applying the greater resources of the system to each hospital's QAPI program and/or infection control program), we believe a system might be able to more efficiently and effectively disseminate innovations, solutions, and best practices for patient care to each of its member hospitals through these respective unified programs. The Health Research and Educational Trust, in partnership with the American Hospital Association in a March 2010 publication entitled, ''A Guide to Achieving High Performance in Multi-Hospital Health Systems,'' identified specific best practices associated with health systems (*http://www.hpoe.org/Reports-HPOE/highperformance3.2010.pdf*). The publication stated that ''due to the size and breadth of their organizations, multi-hospital health system leaders have significant impact on the quality of health care in the United States. More than half of all U.S. hospitals belong to multi-hospital health systems, and about 60 percent of all hospital admissions occurs in system hospitals. While a wide range of quality improvement mechanisms can be applied in individual hospitals, there has been a lack of actionable information that leaders of multi-hospital systems can leverage to improve quality across their systems.''

Therefore, we propose to apply this same level of flexibility and regulatory burden reduction to a hospital's QAPI program as an option for system governing bodies that directly control and are legally responsible for two or more separately certified hospitals. As with our allowances for system governing bodies and unified medical staffs noted previously, we believe that system governing bodies that are legally responsible for two or more separately certified hospitals should be given the flexibility to determine which model of a QAPI program works best for their individual member and separately certified hospitals. We also believe that, in addition to the efficiencies that might be gained in the management and administration of QAPI programs through the increased resources of the hospital system, there might also be significant improvements in patient safety and outcomes to be achieved through such resources. Allowing for a unified and integrated QAPI program for its member hospitals would provide a system governing body with the needed flexibility and ease of administration to more readily apply the best practices and innovations learned and developed at one hospital to other hospitals subject to the same system governing body that might be facing the same problem-prone areas of patient care. We believe that by allowing system governing bodies this regulatory option, greater communication between member hospitals would be fostered so that a culture of patient safety and quality care could then be more fully integrated throughout the system. Given this flexibility and opportunity for integration, we believe that member hospitals subject to the same system governing body would replace the approach of each hospital operating within its own ''silo,'' a still all-too-

common operating standard, even within multi-hospital systems, that thwarts advances and innovations in improving patient care across the system.

We propose a new standard at § 482.21(f), ''Unified and integrated QAPI program for multi-hospital systems''. We would allow that for a hospital that is part of a hospital system consisting of two or more separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, the system governing body could elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that: The unified and integrated QAPI program was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and the unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed. Our expectation is that the focus on quality assessment, performance improvement, and patient safety within a certified hospital that is part of a unified and integrated QAPI program would be maintained and enhanced through the benefits of such integration.

2. Medical Staff, Medical Records Services, and Surgical Services (§§ 482.22, 482.24, and 482.51)

Hospital Medical History and Physical Examination Requirements

The current CoP at § 482.22, ''Medical Staff,'' requires that a hospital have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital. At § 482.22(c)(5), the hospital medical staff bylaws must include a requirement that a H&P be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The bylaws must also include a requirement that an updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the H&P are completed within 30 days before admission or registration. These medical staff bylaws requirements addressing patient H&Ps form the basis for similar requirements in the hospital CoPs at § 482.24, ''Medical Record Services,'' and § 482.51, ''Surgical Services.''

Current hospital H&P requirements were proposed and finalized between 2005 and 2007, and similar ASC requirements were finalized 1 year later. According to a February 28, 2017, Centers for Disease Control and Prevention (CDC) National Health Statistics Report (Hall MJ, Schwartzman A, Zhang J, Liu X. Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010. National health statistics reports; no. 102. Hyattsville, MD: National Center for Health Statistics. 2017), in 2010, 28.6 million ambulatory surgery visits to hospitals and ASCs occurred, with an estimated 48.3 million surgical and nonsurgical procedures performed. The report also states that an estimated 25.7 million (53 percent) ambulatory surgery procedures were performed in hospitals and 22.5 million (47 percent) were performed in ASCs during this time. Further, the report found that the most frequently performed procedures (for both ASCs and hospital outpatient/ambulatory surgery departments) included endoscopy of large intestine (4.0 million), endoscopy of small intestine (2.2 million), extraction of lens (2.9 million), insertion of prosthetic lens (2.6 million), and injection of agent into spinal canal (2.9 million). These statistics, which also show similarities between the characteristics of patients seen by ASCs and hospital outpatient/ambulatory surgery departments, combined with the evidence already discussed in section II.B.2, ''Patient Admission, Assessment and Discharge'' (§ 416.52(a)(1), (2), (3) and (4)) have led us to conclude that we should propose a less burdensome option for the assessment of a patient prior to a hospital outpatient/ambulatory surgery or procedure for specific patients and procedures.

Because the hospital H&P requirements apply to all hospital patients (not just ambulatory surgery patients, as in ASCs) and because these requirements are contained under three separate CoPs, any proposed hospital requirements for pre-surgical assessments in lieu of the current requirements for a comprehensive H&P would need to be structured somewhat differently than those proposed for ASCs. However, we are basing certain aspects of the proposed hospital requirements on those proposed for ASCs in order to take into account some of the similarities of the two provider types.

We would revise the current requirements at § 482.22(c)(5)(i) and (ii) with respect to medical staff bylaws to allow for an exception under the proposed paragraph (c)(5)(iii). We are retaining the current language in paragraphs (c)(5)(i) and (ii) that the H&P, and any update to it, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. We propose to include this same language regarding who can complete and document the assessment in the proposed provision at § 482.22(c)(5)(iii). This provision would require the medical staff bylaws to state that an assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii)) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The proposed paragraphs (c)(5)(iii) and (iv) would require the medical staff to develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) would apply. We are also proposing a new requirement at paragraph (c)(5)(v) for a medical staff that chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) would apply. Under this proposed paragraph, if the medical staff exercised the option to perform a simplified assessment in some cases, the written policy would have to indicate the specific outpatient surgical or procedural services to which it applied. The policy for each procedure would

need to indicate the hospital's consideration of patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure; nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and applicable State and local health and safety laws.

In order to make clear that this proposed requirement would be an option that a hospital and its medical staff could elect to use at their discretion, we propose language that states ''the provisions of paragraphs (c)(5)(iii), (iv), and (v) do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs (c)(5)(i) and (ii) for all patients.'' In other words, a hospital and its medical staff would be free to exercise their clinical judgment in determining whether a policy for identifying specific patients as not requiring a comprehensive H&P (or any update to it) prior to specific outpatient surgical or procedural services, and instead requiring only a pre-surgical assessment for these patients, would be their best course. Or, if a hospital and its medical staff decided against such a policy, then only the current H&P and update requirements (at §§ 482.22, 482.24, and 482.51) would continue to apply and the proposed requirements for this CoP, as well as those proposed for §§ 482.24 and 482.51, would not apply.

For the current CoP at § 482.24, ''Medical Record Services,'' we would revise the provisions at § 482.24(c)(4)(i)(A) and (B) regarding an H&P and its update to allow for an exception under proposed paragraph (c)(4)(i)(C) where are proposing to add a new requirement that, if applicable, the medical record would have to document assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) after registration, but prior to surgery or a procedure requiring anesthesia services, for specific outpatient surgical or procedural services.

The current CoP at § 482.51, ''Surgical Services,'' contains provisions at § 482.51(b)(1)(i) and (ii) that require, prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies that a medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration an updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration. We are revising these requirements to allow for an exception to them under proposed paragraph (b)(1)(iii), where we propose a new requirement that, prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies, an assessment of the patient must be completed and documented after registration (and in lieu of the requirements of paragraphs (b)(1)(i) and (ii)). This proposed requirement would only apply in those instances when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

As we did in the ASC section's discussion of these proposed changes to the H&P requirements, we request comment on whether there are any evidence-based exceptions or specific guidelines, such as for particular patient conditions or surgical procedures, that would prohibit this level of discretion for determining those hospital outpatient surgery patients who would not require a comprehensive H&P prior to outpatient surgeries or procedures.

Contact: CDR Scott Cooper, USPHS, 410–786–9465.

3. Medical Staff: Autopsies (§ 482.22(d))

In the June 1986 final rule, Medicare and Medicaid Programs, Conditions of Participation for Hospitals (51 FR 22010), we finalized a regulation to recommend that a hospital's medical staff attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Hospitals are further required to define a mechanism for documenting permission to perform an autopsy, and they must have a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. In that final rule, we stated that autopsies were an essential educational tool which contributed to the quality of care furnished by a hospital. Medical-legal investigative autopsies are conducted by a coroner's or medical examiner's office to determine the circumstances under which someone died and combine a scientific inquiry into a death under a coroner's or medical examiner's legal jurisdiction (*https://www.cdc.gov/phlp/publications/topic/coroner.html*).

Although the regulations specify that hospitals should attempt to secure permission to perform autopsies in certain cases, each state has established specific standards, laws, and regulations regarding the performance of autopsies for medical-legal investigative purposes for hospital patients. According to CDC's Public Health Law Program, each State sets its own standards for what kinds of deaths require investigation and its own professional and continuing education requirements for individuals carrying out these investigations. For example, the Medicolegal Death Investigation system for the state of New York specifies the use of coroners and medical examiners, who have specific medical and residency qualifications. Maine's Medicolegal Death Investigation system only specifies the role of a medical examiner. Unlike the regulations of the individual States, § 482.22(d) does not provide specifics on who should perform an autopsy, nor does it delve into the specifics of the medical-legal investigation process. As with all other CoPs, our intention was not to be overly prescriptive or overly burdensome in our requirements. In this case, the individual States have more specific requirements than the CoPs.

After reexamining this CoP, and in an effort to reduce duplicative or redundant requirements for hospitals, we believe that it is appropriate to remove the requirement at § 482.22(d). We believe that more detailed, specific requirements regarding medical-legal investigations and autopsies for hospitals are more appropriately and more effectively covered by the individual State laws in which the hospital is located. Therefore, we propose to remove the requirement at § 482.22(d). However, we continue to believe that the performance of autopsies further advances medical knowledge.

Contact: Alpha-Banu Wilson, 410–786–8687.

4. Infection Control (§ 482.42)

Similar to our proposal for a unified and integrated QAPI program for multi-hospital systems previously discussed, we believe that the same level of flexibility and regulatory burden reduction can be applied to a hospital's infection control program. We firmly believe that the same efficiency of administration, and improved patient outcomes, patient safety, and quality of care would be achieved in the infection control realm through a consistent system-wide approach as would be

allowed by this proposed rule. Our expectation is that the focus on infection control within a certified hospital that is part of a unified and integrated infection control program would be maintained and enhanced through the benefits of such integration, and that the trajectory toward continued reductions in infections would be continued.

Therefore, we propose a new standard at § 482.42(c), ''Unified and integrated infection control program for multi-hospital systems.'' Like the proposed requirements for a unified and integrated QAPI program, the proposed standard for infection control would allow that for a hospital that is part of a hospital system consisting of multiple separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, such system governing body could elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision was in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals met all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that the unified and integrated infection control program: (1) Was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; (2) established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration; (3) had mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and (4) designated a qualified individual(s) at the hospital with expertise in infection prevention and control to be responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control, and for providing infection prevention education and training to hospital staff.

We are specifically seeking comment on whether there are any other programs currently required under the CoPs for each separately certified hospital, beyond the QAPI and Infection control programs proposed here, that stakeholders believe would likewise be better managed under a system governing body legally responsible for the conduct of each separately certified hospital.

Contact: CDR Scott Cooper, USPHS, 410–786–9465.

5. Special Requirements for Hospital Providers of Long-Term Care Services (''Swing-Beds'') (§ 482.58(b)(1), (4), (5), and (8), and Identical CAH Requirements: § 485.645(d)(1), (4), (5), (6), and (7))

Section 1883 of the Act permits certain small, rural hospitals to enter into a swing-bed agreement, under which a hospital or CAH can use its beds as needed, to provide either acute or SNF care. Swing-beds are beneficial when a patient is ready to leave the acute care level of a hospital stay, but still requires further skilled nursing care. They are often the only option in rural areas to provide this level of care. As defined in our regulations, a swing-bed hospital is a hospital or CAH participating in Medicare that has CMS approval to provide post-hospital SNF care and meets certain requirements. Hospitals providing swing-bed services must meet all of the requirements at 42 CFR part 482, which includes the swing-bed requirements at § 482.58 for patients receiving swing-bed services, and CAHs providing swing-bed services must meet all of the requirements at 42 CFR part 485, subpart F, which includes the swing-bed requirements at § 485.645 for patients receiving swing-bed services.

The hospital CoPs at § 482.58(a)(1) and (2) specify that hospitals providing swing-bed services must be located in a rural area and have less than 100 beds. Section 482.58(a)(1) excludes from the count beds for newborns and beds in intensive care type inpatient units, and § 482.58(a)(2) requires that the hospital be located in rural area, which includes all areas not delineated as ''urbanized'' areas by the Census Bureau, based on the most recent census.

The CAH CoPs at § 485.645(a)(2) state that a CAH must not maintain more than 25 inpatient beds that may be used for the provision of inpatient or swing-bed services, and as required at § 485.635(b)(1)(ii), the CAH must furnish acute care inpatient services to patients who present to the CAH for treatment, so long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH (State Operations Manual, Appendix W).

Hospitals and CAHs must both meet eligibility requirements to be granted approval from CMS to provide swing-bed services. The swing-bed requirements within the hospital and CAH CoPs include a subset of cross-referenced long-term care requirements contained in 42 CFR part 483, subpart B, for which hospital and CAH swing-bed providers are surveyed as they are for all of the CoPs in their respective programs.

The long-term care requirements under 42 CFR part 483 frequently reference residents given the average length of stay in long-term care facilities (28 days for skilled nursing facilities and 835 days for nursing homes) (Medicare Skilled Nursing Facility (SNF) Transparency Data (CY2013), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-09.html#*; Centers for Disease Control and Prevention, Nursing Home Care FastStats, *https://www.cdc.gov/nchs/data/series/sr_03/sr03_038.pdf*). However, individuals receiving swing-bed services in a hospital or CAH are receiving SNF services and generally have shorter length of stays, with an the average length of stay of 11.4 days (Centers for Medicare & Medicaid Services, Office of Enterprise Data and Analytics, 2016). Note that this is still less than the average 28-day length of stay in a SNF. While we understand that some patients receiving swing-bed services in a hospital or CAH may have longer than average length of stays, we have determined that some of the cross-referenced long-term care requirements for hospitals and CAH swing-bed providers are unnecessary and unduly burdensome given their focus on ''residents'' and longer length of stays. Thus, we propose to remove the following requirements:

- *§§ 482.58(b)(1) and (c) and 485.645(d)(1) (incorporating long-term care facility requirements at § 483.10(f)(9):* Under our current regulations at § 483.10(f)(9), the resident has a right to choose to or refuse to perform services for the facility, and the facility must not require a resident to perform services for the facility. Regulations at §§ 482.58(b)(1) and 485.645(d)(1) incorporate this resident right by reference. The resident may perform services for the facility, if he or she chooses.

The current requirement for LTCFs also states that residents of these providers who are receiving swing-bed services who choose to perform services for the facility may do so when the facility has documented the need or desire for the resident to work in the plan of care; the plan specifies the nature of the services performed and whether the services are voluntary or paid; compensation for paid services is

at or above prevailing rates; and the resident agrees to the work arrangement described in the plan of care. Provided that those receiving hospital and CAH swing-bed services are not residents and spend a limited amount of time receiving swing-bed services, we have determined that this is an unduly burdensome requirement. Swing-bed services are transitional SNF-level services provided on a temporary basis. As a result, only a limited number of the SNF requirements are applicable to these patients. Therefore, we believe that it is unlikely that patients receiving hospital and CAH swing-bed services would be assigned a job and given an opportunity to provide services at the hospital or CAH due to their relatively short length of stay. With the proposed removal of this requirement, a hospital or CAH may permit patients receiving swing-bed services to provide services at the facility upon mutual agreement between the patient and the facility; thus, we believe that this requirement is unnecessary. We expect hospital and CAH swing-bed providers who do offer patients the option of providing services for the facility to have current policies and procedures that reflect this policy that includes protocol for establishing an agreement between the two parties. In addition, in the absence of these requirements, we believe patients' rights requirements for hospitals at § 482.13 and CAHs providing swing-bed services at § 485.645(d)(3) (which incorporates the long-term care requirements that patients be free from abuse, neglect and exploitation) would address such situations. We would monitor for any unintended consequences, as well as through evaluation of complaints that might be submitted regarding involuntary work performed by patients receiving swing-bed services in hospitals and CAHs. We would also ensure patient protections were maintained via the survey process and the process used to determine allegations of non-compliance with Federal or State requirements.

- *§§ 482.58(b)(4) and 485.645(d)(4) (incorporating long-term care facility requirements at § 483.24(c)):* The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities and the activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional.

Similar to the requirements noted previously, we believe that this requirement is also unnecessary and burdensome for hospitals and CAHs, as patients receiving swing-bed services in a hospital or CAH are not long term residents of the facility and generally only receive swing-bed services for a brief period of time for transition after the provision of acute care services. We expect that for those patients who receive swing-bed services for an extended period of time, their nursing care plan—as required under § 482.23(b)(4) for hospitals and § 485.635(d)(4) for CAHs—is based on assessing the patient's nursing care needs and will support care that holistically meets the needs of the patient, taking into consideration physiological and psychosocial factors.

- *§§ 482.58(b)(5) and 485.645(d)(5) (incorporating long-term care facility requirements at § 483.70(p)):* Any facility with more than 120 beds must employ a qualified social worker on a full-time basis.

We propose to revise the requirements at §§ 482.58(b)(5) and 485.645(d)(5) for hospitals and CAHs. The requirement that hospital and CAH swing-bed providers with more than 120 beds employ a full-time social worker is not applicable to either provider type. In accordance with the hospital and CAH swing-bed requirements, hospital swing-bed providers are not permitted to have more than 100 beds while CAH swing-bed providers are not permitted to have more than 25 beds for the provision of inpatient or swing-bed services. Based on feedback from stakeholders, removing this requirement would eliminate confusion for providers and accreditation organizations.

- *§§ 482.58(b)(7) and 485.645(d)(7) (incorporating the long-term care facility requirement at § 483.55(a)(1)):* Under our long-term care facility requirements, the facility, must provide or obtain from an outside resource, in accordance with § 483.70(g), routine and emergency dental services to meet the needs of each resident. We believe that this requirement is unnecessary and unduly burdensome for hospital and CAH swing-bed providers, as patients receiving swing-bed services in a hospitals or CAHs are not ''generally long term residents'' of the facility and are meant to receive swing-bed services for a brief period of time for transition after the provision of acute care services. The American Dental Association recommends regular dental checkups at least once a year for routine dental care for adults over 60 years of age. With an average length of stay in a hospital or CAH swing-bed of 11.4 days and an average daily swing-bed census of 2 patients, we believe that it is unlikely that there is a need for routine dental services that cannot be provided on an outpatient basis. We expect that any required dental services that necessitate immediate treatment would be considered an emergency and would be addressed accordingly. In addition, the American Dental Association recommends that routine dental care be obtained at least every 6 months, which greatly exceeds that average length of stay in a hospital or CAH swing-bed. However, hospitals and CAHs are required to provide care in accordance with the needs of the patient that have been identified in such patients' plans of care; this could include non-emergency dental care. We expect that hospital swing-bed providers are currently addressing the emergent dental care needs of their patients under the existing hospital CoP at § 482.12(f)(2), which requires that hospitals have written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate. Similarly, we expect that CAH swing-bed providers are currently addressing the emergent dental care needs of their patients under the existing emergency services CoP at § 485.618, which requires CAHs to provide emergency care necessary to meet the needs of its inpatients and outpatients. As a result, we believe that this portion of the requirement is duplicative, given the current CoP requirements.

Contact: Kianna Banks, 410–786–3498.

6. Special Requirements for Psychiatric Hospitals (§ 482.61(d))

Section 482.61(d) of our regulations, as finalized in the June 1986 final rule (51 FR 22050), requires that progress notes be documented by the doctor of medicine (MD) or doctor of osteopathy (DO) responsible for the care of the patient and, when appropriate, others significantly involved in active treatment modalities. ''Others significantly involved in active treatment modalities'' has been interpreted as staff from other disciplines, such as rehabilitative therapy and psychology, which are significantly involved in active treatment modalities and interventions. The intent of this requirement is to assure that the patient's medical record contains documentation of the patient's response to treatment planning and course of treatment. This documentation also serves to apprise all staff about patient's progress and any new problems or regression. We believe that the intent of the requirement to record progress notes in the patient's medical record continues to be an appropriate regulatory requirement. However, we

believe that as currently written and implemented, this requirement requires clarification. We believe that non-physician practitioners, including physician assistants, nurse practitioners, psychologists, and clinical nurse specialists, when acting in accordance with State law, their scope of practice, and hospital policy, should have the authority to record progress notes of psychiatric patients for whom they are responsible. Therefore, we propose to allow the use of non-physician practitioners or MD/DOs to document progress notes of patient receiving services in psychiatric hospitals.

Contact: Kianna Banks, 410–786–3498.

We are seeking public comment on all of the proposed hospital changes. In addition, we note that we seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on hospitals and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the following 2017 prospective payment regulations for hospitals:

- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Outpatient Prospective Payment System/Ambulatory Surgical Center proposed rule (*https://www.regulations.gov/docket?D=CMS-2017-0091*).
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System (*https://www.regulations.gov/document?D=CMS-2017-0059-0002*).
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System (*https://www.regulations.gov/document?D=CMS-2018-0053-0002*).

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

E. Transplant Centers

Transplant programs, located within a transplant hospital that has a Medicare provider agreement, provide transplantation services for a particular organ type. Transplant programs must comply with the transplant center CoPs, located at §§ 482.72 through 482.104, and with the hospital CoPs. There are several types of transplant programs including heart, lung, liver, and kidney. Intestine, pancreas, and multi-organ transplants are performed within existing transplant programs. For the purposes of this discussion, we define a transplant center as a group of transplant programs that are located in a transplant hospital. A transplant program is a component of the transplant center, within a transplant hospital, that provides transplantation for a particular type of organ. Transplant programs are surveyed for compliance with the CoPs.

This proposed rule uses the term ''transplant center'' when discussing the current requirements and language used in the regulations. In accordance with our proposed nomenclature change, discussed later in this proposed rule, the term ''transplant program'' is widely used throughout the preamble and in the proposed regulation text.

Section 1881(b)(1) of the Act sets out our authority for the Secretary to prescribe regulations for facilities furnishing end stage renal disease care to beneficiaries, including renal transplant centers. Section 1861(e)(9) of the Act permits the Secretary to issue regulations for the health and safety of individuals furnished services in hospitals.

In response to the relative scarcity of donated organs compared to the number of people on transplant waitlists and the critical need to use these limited resources efficiently, we published a final rule that established CoPs for transplant centers on March 30, 2007, (Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants) which codified requirements for approval and re-approval of transplant centers. We also placed Medicare-approved transplant centers under the survey and certification enforcement process we use for all other providers and suppliers of Medicare items and services (72 FR 15198). The transplant center CoPs include data submission, clinical experience, outcome, and process requirements for approval and re-approval of transplant centers. The requirements focus on an organ transplant program's ability to perform successful transplants and deliver quality patient care, as evidenced by outcomes as well as sound policies and procedures. The CoPs include requirements to protect the health and safety of both transplant recipients and living donors.

We have continued to review and analyze the effectiveness of the transplant center CoPs, the effects of interpretive guidance, and the data derived from surveys of transplant programs. We also received comments from various stakeholders within the transplant center community that detailed the impacts of the implementation of the CoPs on transplant programs and transplant recipients. Upon further review, and taking into account input from various stakeholders, we believe that it is appropriate and necessary to revise the transplant center CoPs in order to reduce provider burden, increase long-term savings to the Medicare program, and eliminate obsolete or unnecessary requirements, while also continuing to protect the health and safety of transplant recipients and living donors.

Furthermore, we believe that revising the transplant center CoPs will positively impact organ donation and transplantation in the United States by increasing the number of transplants performed each year and increasing the organ utilization rate, for reasons we discuss in further detail below. According to the Organ Procurement and Transplantation Network (OPTN) 33,610, organ transplants were performed and 15,948 donors (both living and deceased) provided organs in the United States in 2016. However, as of the writing of this proposed rule, 117,104 people still need a lifesaving organ transplant in 2017 (number represents total waiting list candidates, *https://optn.transplant.hrsa.gov/,* July 2017). While strides are being made to improve organ donation and increase the number of organ transplants in the United States, there continues to be a shortage of organs.

Therefore, we propose to revise the transplant center CoPs, as follows:

1. Special Requirement for Transplant Centers (§§ 482.68 and 482.70)

Section 482.68 generally describes the requirements that a transplant center must meet in order to participate in the Medicare program; section § 482.70 sets out definitions of terms used in the regulations. Specifically, in addition to meeting all the CoPs as a hospital, a transplant center must meet the CoPs specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services. Throughout the regulation, we use terminology relevant to transplantation and organ procurement to describe transplant centers, programs, living donors, and transplant center recipients. Because the terminology currently used in the regulation is not consistent with current nomenclature used throughout the transplant community and by the OPTN, Scientific Registry of Transplant Recipients (SRTR), and the Department of Health and Human Services (HHS), we propose to update the terminology within the hospital regulation at part 482 and the transplant regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61, for clarification and consistency. Specifically, we propose a nomenclature change which would:

- Replace the term transplant ''center'' in the regulation language with transplant ''program'' (each organ type would be a transplant program). A transplant program is located within a transplant hospital that provides transplantation services for a particular type of organ. Since individual transplant programs are surveyed for compliance with the CoPs, using the term transplant program throughout the regulation better aligns with current surveyor practice and will reduce provider confusion. In order to provide further clarity, we are also proposing to update the definitions at § 482.70.
- Consistently use Independent Living Donor Advocate (ILDA) throughout the regulation.
- Change ''beneficiaries'' to ''recipients''.

Since these changes would make our terms consistent with the terminology utilized by the OPTN and the transplant community, we believe these proposed changes would reduce provider confusion.

2. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers (§ 482.82)

Section 482.82 requires that transplant centers that are applying for Medicare re-approval meet all data submission, clinical experience, and outcome requirements in order to be re-approved. In the March 2007 final rule (72 FR 15198), we also finalized these requirements for initial Medicare approval of transplant centers, as described in § 482.80. Since the publication of the final rule, several studies have been published that examine the impact of these requirements on transplantation and organ utilization in the United States. A 2016 article published in the American Medical Association Journal of Ethics concluded that ''using measured outcomes for punitive purposes may have resulted in significant unintended consequences'' and that ''transplant professionals will, by necessity, adapt practice to minimize the risk of regulatory citation and loss of transplant volume'' which contributes to ''lower transplant rates (typically among higher-risk candidates)'' and increased organ discard of marginal organs. (Adler, Joel T. and Axelrod, David A. Regulations' Impact on Donor and Recipient Selection for Liver Transplantation: How Should Outcomes be Measured and MELD Exception Scores be Considered, AMA Journal of Ethics, Vol. Volume 18, Number 2: 133–142. Doi: 10.1001/journalofethics.2016.18.02. pfor1–1602, February 2016.).

Another study linked performance evaluations to transplant volume in kidney transplant centers. The authors observed that centers that had low performance evaluations were more likely to have fewer kidney transplants than other kidney transplant centers. The study stated that kidney transplant centers that were identified with poor outcomes ''may be more likely to have staff turnover which may lead to declines in transplant volume'' and ''[c]enters that have been evaluated with lower performance may generally become more conservative in overall acceptance rates of candidates and donor organs'' (Schold, JD, et al. The Association of Center Performance Evaluations and Kidney Transplant Volume in the United States. *American Journal of Transplantation 2013; 13: 67–75.* doi: 10.1111/j.1600–6143.2012.04345, 2013.).

Another study covering over 90,000 liver transplant candidates concluded that the transplant center regulations that were finalized in the March 2007 final rule (72 FR 15198) increased the likelihood that liver transplant candidates would be removed from the liver transplant candidate waitlist and that this policy change led to the sickest patients being increasingly ''denied this lifesaving procedure while transplant mortality risks remain unaffected.'' The study found that the 2007 regulations had the effect of altering waitlist management and clinical decision making, thereby increasing the removal of the sickest patients from the waitlist. The impacts were seen through a 16 percent increase in delisting of patients due to the severity of their illness after the implementation of the 2007 regulation, and likelihood of being delisted continued to increase thereafter. The authors concluded that the 2007 regulation, which aimed to improve patient outcomes, had the consequence of instead failing to show any benefit to liver transplant patients. The authors suggested that future national policy decisions consider rebalance of the waitlist and transplant outcomes scale (Dolgin, Natasha H. et al. Decade-Long Trends in Liver Transplant Waitlist Removal Due to Illness Severity: The Impact of Centers for Medicare and Medicaid Services Policy. Journal of the American College of Surgeons. Volume 222, Issue 6, Pages 1054–1065. DOI: *http://dx.doi.org/10.1016/j.jamcollsurg.2016.03.021,* June 2016.).

Another study of kidney transplantation found that most of the increases in the discard rate from 1988 to 2009 could be explained by recovery of organs from an increasing donor pool and changes in ''pumping'' or perfusion practices. ''However, the presence of an unexplained, residual increase suggests behavioral factors (*e.g.,* increased risk aversion) . . . may have played a role.'' (Darren E. Stewart, et al. Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. Transplantation. 2017; 101: 575–587.).

A different approach was taken in a recent study using data from 2000 to 2015. This study found that by comparing donors from whom one only one kidney was discarded and the other was transplanted reasons for discard could be better assessed. In this study ''a large number of discarded kidneys were procured from donors whose contralateral kidneys were transplanted with good post-transplant outcomes.'' It found that when two kidneys were retrieved from a deceased donor, and one of the two was discarded and the other used in a transplant, it was often the case that these ''discarded organs could have possibly demonstrated excellent performance if transplanted'' and ''the use of even a fraction of them could substantially reduce the number of patients who never receive an organ.'' As for the cause of these discards, the authors analyzed several factors and stated that ''the current report card system for transplant centers in the

United States . . . creates a disincentive to broader organ acceptance for centers concerned about payment penalties'' and that ''realignment of [these] incentives to promote more appropriate utilization is a key factor in reducing discards.'' (Syed Ali Husain, et al. Characteristics and Performance of Unilateral Kidney Transplants from Deceased Donors. Clinical Journal American Society of Nephrology 13: 2018.)

We also received comments and feedback from pertinent stakeholders in the transplant community that align with the conclusions of these studies. For instance, UNOS has presented at public meetings that up to ⅓ of kidneys that are discarded could be successfully transplanted. Furthermore, the transplant community has noted that transplant programs may not use these kidneys due to the perception that they are of higher risk and that the utilization of these kidneys may lead to outcomes non-compliance under § 482.82. These programs have avoided using these kidneys for fear of non-compliance with the CoPs and potential Medicare termination of the program, despite evidence to the contrary that demonstrates that the use of these kidneys would not pose a problem for transplant recipients. The transplant community has therefore concluded that the regulations have led to behavioral changes in organ selection and transplantation on patients with fewer comorbidities and lower risk. This has resulted in transplant programs potentially avoiding performing transplant procedures on certain patients and many organs going unused.

While it was our intent to ensure quality of care in transplant programs with the implementation of the regulations in § 482.82, we acknowledge that the final regulation may have caused unintended consequences that impact transplantation and transplant programs in the U.S. Given the findings of published studies and articles, and the public feedback we have received, we believe that it is appropriate to remove these requirements for re-approval of transplant programs in the Medicare program.

Therefore, we propose to remove the requirements at § 482.82 that require transplant centers to submit data (including, but not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant beneficiary registration and follow-up, and living donor registration and follow-up), clinical experience, and outcome requirements for Medicare re-approval, and make conforming changes to § 482.102(a)(5) ''Condition of participation, Patient and living donor rights'' and § 488.61 ''Special Procedures for Approval and Re-Approval of Organ Transplant Centers.'' Although we propose to remove these requirements, we continue to strongly believe that transplant programs should focus on maintaining high standards that protect patient health and safety and produce positive outcomes for transplant recipients. Therefore, we will continue to monitor and assess outcomes, after initial Medicare approval, through the transplant and hospital QAPI programs. In addition, quality of care will be monitored by assessing the other transplant program CoPs, including §§ 482.72 through 482.104. We also encourage transplant programs and their respective hospitals' QAPI programs to conduct thorough analyses of adverse events, document such events, and implement improvement activities to prevent recurrences. We further note that transplant programs must continue to comply with the CoPs at §§ 482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under § 482.80. We believe this proposal will eliminate provider disincentives for performing transplantations and will lead to increased transplantation opportunities for patients on the waitlist; improved organ procurement for transplantation; greater organ utilization; lifesaving effects, reduced burden on transplant programs; and reductions in costs to both public and private insurance.

We are seeking public comment on the removal of this requirement.

3. Special Procedures for Approval and Re-Approval of Organ Transplant Centers (§ 488.61(f) Through (h))

Section 488.61 describes the survey, certification, and enforcement procedures for transplant centers, including the periodic review of compliance and approval as set out at § 488.20. Section 488.61(f) through (h) set out the process for our consideration of a transplant center's mitigating factors in initial approval and re-approval surveys, certifications, and enforcement actions for transplant centers. The provisions also set out definitions and rules for transplant systems improvement agreements. We propose to remove the requirements at § 488.61(f) through (h) for mitigating factors and transplant systems improvement agreements for the re-approval process for transplant centers. This change is complementary to the proposed removal of § 482.82, described previously. We believe that repeal of these paragraphs would significantly reduce transplant programs' regulatory burden by no longer requiring them to submit mitigating factors applications or enter into systems improvement agreements for outcomes non-compliance (for re-approval surveys, certifications, and enforcement actions for transplant programs). Transplant programs will continue to be afforded the opportunity to submit mitigating factors or to enter into transplant systems improvement agreements during the initial application process to the Medicare program under § 488.61 (f) through (h).

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on transplant programs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System proposed rule. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0055.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Alpha-Banu Wilson, 410–786–8687.

F. Home Health Agencies

Home health services are covered for the elderly and disabled under the

Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act). These services, provided under a plan of care established and periodically reviewed by a physician, must be furnished by, or under arrangement with, a home health agency (HHA) that participates in the Medicare or Medicaid programs. Services are provided on a visiting basis in the beneficiary's home, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered professional nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical residency training program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when the services involve equipment too cumbersome to bring to the home.

Under the authority of sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in regulations at 42 CFR part 484, Home Health Services.

1. Patient Rights (§ 484.50(a)(3) and (c)(7))

Section 484.50(a)(3) of the January 2017 HHA CoP final rule (82 FR 4504), effective January 13, 2018, requires HHAs to provide verbal (meaning spoken) notice of the patient's rights and responsibilities in addition to the requirement to provide such notice in writing. Section 1891(a)(1)(E) of the Act requires additional oral notice of rights for specified information as follows:

- All items and services furnished by (or under arrangements with) the agency for which payment may be made under Medicare,
- The coverage available for such items and services under Medicare, Medicaid, and any other Federal program of which the agency is reasonably aware,
- Any charges for items and services not covered under Medicare and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and
- Any changes to the charges or items and services set forth in the previous bullets.

Section 1891(a)(1)(F) of the Act requires that HHAs provide the notice of patient rights in writing.

The requirements at § 484.50(a)(3) implement these statutory requirements, and require spoken notice of all patient rights, rather than limiting such notice to those rights specified in the Act. On July 28, 2017, we published a proposed rule entitled ''CY 2018 Home Health Prospective Payment System Rate Update; Home Health Value Based Purchasing Model; and Home Health Quality Reporting Requirements'' (82 FR 35270) that solicited public comments on ways to reduce regulatory burden. In response to this solicitation, we received feedback from HHA stakeholders that the requirement to provide verbal notice of all rights to patients and their representatives was overly burdensome to the HHA clinicians that would be required to discuss the notice with patients when they could be furnishing hands-on patient care during that time, and lacked evidence that such explanations would result in improvements to patient safety or care. Furthermore, comments received encouraged us to reexamine all burdens in the January 2017 HHA CoP final rule to weigh potential benefits against estimated costs.

We believe that the concerns expressed by commenters have merit. In light of this information, we believe that any benefits of this requirement are outweighed by the burdens imposed by this requirement. For this reason, we propose to delete the requirement that HHAs must provide verbal notification of all patient rights. This change would be consistent with the notice of patient rights requirements for other outpatient provider types, such as hospices, ambulatory surgery centers, and community mental health centers, for which written notice of patient rights is the only requirement. We propose to limit the verbal notification requirements to those requirements set out in section 1891(a)(1)(E) of the Act for which verbal notification is mandatory. We propose to revise § 484.50(c)(7) to implement this more limited verbal notification requirement. Revised § 484.50(c)(7) would require HHAs to verbally discuss HHA payment and patient financial liability information with each HHA patient as described above.

This change would not prevent states or Accrediting Organizations (AOs) from independently establishing and enforcing verbal notification requirements for all patient rights for purposes other than the HHA CoPs, nor would it prohibit HHAs from providing such verbal notification of all patient rights in the absence of Federal regulation. Furthermore, this change would not alter the other requirements at § 484.50(a), which requires HHAs to provide the notice of patient rights in writing, nor would it alter the requirements at § 484.50(f), Accessibility, which requires HHAs to provide information to patients in plain language and in a manner that is both accessible and timely to: (1) Persons with disabilities in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, and (2) persons with limited English proficiency. While HHAs would no longer be required to provide a verbal notification of all patient rights, we would continue to expect that HHAs answer any questions from patients or their representatives regarding the content of the written notice of rights. We believe that this proposed change would continue to provide adequate notice to patients while reducing burden on HHAs.

2. Home Health Aide Services (§ 484.80(h)(3))

Section 484.80(h)(3) of the January 2017 HHA CoP final rule (82 FR 4504) requires that, when a supervisory visit identifies a deficiency in a home health aide's skills, the HHA must conduct, and the aide must complete, a full competency evaluation to assess all aide skills and identify any other skill deficiencies that were not identified while observing the aide performing care with a patient. In public comments submitted for the July 2017 proposed rule ''CY 2018 Home Health Prospective Payment System Rate Update'' (82 FR 35270), a commenter suggested that completing a full competency evaluation was overly burdensome for HHAs and aides. Although this comment was not submitted during the proposed rule public comment period for the HHA CoP proposed rule, we believe that the concern expressed by the commenter has merit. In light of this new comment, we reconsidered the requirement, and concluded that a full competency evaluation is unnecessary and overly burdensome when only certain skills have been identified as deficient. We propose to eliminate the requirement to conduct a full competency evaluation, and replace it with a requirement to retrain the aide regarding the identified deficient skill(s) and require the aide to complete a

competency evaluation related only to those skills. This targeted retraining and competency evaluation requirement would reduce the time spent completing competency evaluations and retraining efforts.

3. Clinical Records (§ 484.110(e))

In the January 2017 HHA CoPs final rule (82 FR 4504), effective January 13, 2018, we finalized a requirement, codified at § 484.110(e), that an HHA must make available, upon request, a copy of the patient's clinical record at the next home visit, or within 4 business days (whichever comes first). In response to the July 2017 proposed rule solicitation of public comment on burden reduction via the CY 2018 Home Health Prospective Payment System Rate Update (82 FR 35270), we received feedback from HHA stakeholders that this requirement was impractical for HHAs to comply with because providing the record at the next visit may not allow enough time for HHAs to create a physical or electronic copy of the clinical record content, provide that copy to the next visiting clinician who may not be scheduled to come into the HHA office prior to the visit due to the nature of home based care and the significant travel that HHA clinicians must do in order to make patient visits, and successfully deliver the copy to the patient. The comments suggested that the 4 business day timeline was more practical and is an appropriate regulatory requirement. We agree that providing the record at the next visit is not practical or even possible in some cases. Furthermore, we agree that retaining the 4 business day timeframe is an appropriate regulatory requirement. Therefore, we propose to remove the requirement that the requested clinical record copy must be provided at the next home visit.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on HHAs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective.

We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0100.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Danielle Shearer, 410–786–6617.

G. Comprehensive Outpatient Rehabilitation Facilities (CORFs)—Utilization Review Plan (§ 485.66)

Section 485.51 of our rules defines a Comprehensive Outpatient Rehabilitation Facility (CORF) as a nonresidential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician. As of May 2017, there were 188 Medicare-certified CORFs in the United States. Section 1861(cc)(2)(G) of the Act requires CORFs to maintain utilization review programs. Under this authority, the Secretary has established requirements at § 485.66 with respect to such programs. Currently, § 485.66 requires the CORF to have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

We propose to amend the utilization review plan requirements at § 485.66 to reduce the frequency of utilization reviews. We believe the requirement to implement a utilization review plan 4 times a year is overly burdensome and diverts staff from providing patient care. We propose to require the utilization review plan be implemented annually by the facility, which would allow an entire year to collect and analyze data to inform changes to the facility and the services provided. Changing the requirement from a quarterly to an annual review would not preclude the CORF from implementing their utilization review plan more frequently, if required by facility policy. We believe that an annual utilization review plan will serve as a useful measurement tool for the facility, and that the change from quarterly to annual would not negatively affect patient health and safety.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on CORFs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the 2017 payment regulations. We refer readers to the public comments that were submitted in response to the RFI for the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-0001.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*

• CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*

• FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*

• FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2018-0053-0002.*

• CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*

• FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Jacqueline Leach, USPHS, 410–786–4282.

H. Critical Access Hospitals

1. Organizational Structure (§ 485.627(b)(1))

Current regulations at § 485.627 require CAHs to disclose the names and addresses of its owners, those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with 42 CFR part 420, subpart C. Section 42 CFR part 420, subpart C, sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and sets forth requirements for disclosure of information about a provider's or Part B supplier's owners and those with a controlling interest.

The disclosure of ownership provisions at 42 CFR part 420, subpart C, are also required under the provider agreement rules under 42 CFR part 489. The term ''provider agreement'' is defined in § 489.3 as an agreement between CMS and a provider or supplier to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act (Agreements with Providers of Services; Enrollment Processes). Providers must meet the terms of the agreement to be qualified to participate in the Medicare program.

We propose to remove this disclosure requirement from the CAH CoPs as it is duplicative of requirements for the provider agreement. Specifically, disclosure of individuals with a financial interest in the CAH is a requirement under the provider agreement rules in § 489.12(a)(2) and must be completed during the provider enrollment process. This information must be disclosed on the provider's Medicare enrollment application (Form CMS–855A for CAHs) and the enrollment application must be updated with any changes, such as address changes, practice name or change of ownership of information and must be submitted to CMS. Also note that this is not a requirement in the hospital CoPs under 42 CFR part 482 because it is already a requirement in the provider agreement rules under § 498.12(a)(2).

Contact: Kianna Banks, 410–786–3498.

2. Provision of Services (§ 485.635(a)(4))

Current regulations at § 485.635 require CAHs to review policies and procedures annually. We believe that medical practice has evolved such that we can provide flexibility for facilities to review, correct, or change their policies and procedures. Based on our experience with medical care providers and information from organizations such as the Brookings Institution (*https://www.brookings.edu/testimonies/improving-health-care-quality-the-path-forward/*), the expanded use of Web-based information and resources has fundamentally changed patient care, medical practice, and education. It has enabled providers to easily adjust policies and procedures on an as-needed basis. We believe that a prescriptive requirement to review policies and procedures annually could be eliminated to allow providers to review biennially and update as necessary, or more frequently if needed. For example, we expect providers to update their policies and procedures as needed in response to regulatory changes, changes in the standard of care, or nationally recognized guidelines.

The current CoP at § 485.635(a)(4) requires a CAH to review its policies at least annually by the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1). The policies that are reviewed must include the following:

• A description of the services the CAH furnishes, including those furnished through agreement or arrangement;

• Policies and procedures for emergency medical services;

• Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records;

• Rules for the storage, handling, dispensation, and administration of drugs and biologicals;

• Procedures for reporting adverse drug reactions and errors in the administration of drugs; and

• A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

• Procedures that ensure that the nutritional needs of post-hospital SNF inpatients are met in accordance with recognized dietary practices.

Based on feedback from stakeholders, the prescriptive annual schedule can be burdensome or, in some situations, ineffective. Providers stated that they make annual, monthly and biannual changes to their policies. Some have stated that they make changes as needed or infrequently. They also stated that the time that it took to review the policies varied. Some stated it would take as little as 2 hours while a few stated a much longer period time such as a month, depending on what was being changed. We believe that taking a month would represent a new facility or a facility that is experiencing major restructuring. After a careful review of the varied responses, we propose to provide flexibility and reduce burden by revising the requirement at § 485.635(a)(4) to, at a minimum, only require a biennial review of policies and procedures. The 2-year review would not preclude a facility from conducting a review more frequently if needed or organizing the review such that it would be completed over a 2-year period. Based on our experience with other providers, we believe that this approach would allow CAHs to maintain their health and safety policies in such a manner as to achieve the intended outcomes for all patients. Thus, we propose to change the requirement at § 485.635(a)(4) from ''annual'' to ''biennial''.

Contact: Mary Collins, 410–786–3189.

3. Special Requirements for CAH Providers of Long-Term Care Services (''Swing-Beds'') (§ 485.645(d)(1), (4), (5) and (8))

The special requirements for CAH swing-bed providers are nearly identical to the requirements for hospital providers of swing-bed services. As a result, please refer to the discussion on the special requirements for hospital providers of swing-bed services under section II.D.3 for the details of the proposed changes for these requirements. We propose the following revisions to the CAH swing-bed requirements:

- Revision of § 485.645(d)(1) to remove the cross-referenced long-term care requirement in § 483.10(f)(9), which requires that CAH swing-bed providers to offer residents the right to choose to or refuse to perform services for the facility and prohibits a facility from requiring a resident to perform services for the facility;
- Removal of § 485.645(d)(4), which requires CAH swing-bed providers to provide an ongoing activity program that is directed by a qualified therapeutic recreation specialist or an activities professional who meets certain requirements (cross-referenced long-term care requirement § 483.24(c));
- Redesignation of paragraphs (d)(5) through (9) as (d)(4) through (8), respectively;
- Revision of § 485.645(d)(4) (as redesignated) to remove the cross-referenced long-term care requirement § 483.70(p), which requires that CAH swing-bed providers with more than 120 beds to employ a qualified social worker on a full-time basis; and
- Revision of § 485.645(d)(7) (as redesignated) to remove the cross-referenced long-term care requirement § 483.55(a)(1), which requires CAH swing-bed providers to assist in obtaining routine and 24-hour emergency dental care to its residents.

Contact: Kianna Banks, 410–786–3498.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on CAHs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

I. Community Mental Health Center (§ 485.914(d))

On October 29, 2013, we published a final rule (78 FR 209) that established, for the first time, a set of requirements that Medicare-certified CMHCs must meet in order to participate in the Medicare program. These CoPs ensure the quality and safety of CMHC care for all clients served by the CMHC, regardless of payment source. These requirements focus on a person-centered, outcome-oriented process that promotes quality client care. These CoPs are set forth at 42 CFR part 485 and apply to all Medicare participating CMHCs.

Medicare certified CMHCs provide services to a wide range of clients, from those needing partial hospitalization program (PHP) services to clients needing routine counseling. Partial hospitalization services are an intense level of services needed ''to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization. . . .'' (section 1861(ff)(2) of the Act). As written, the current standard at § 485.914(d) requires the CMHC to update the client comprehensive assessment every 30 days regardless of the client's needs or treatment schedule. This 30 day update of the comprehensive assessment correlates with the CMS PHP payment regulations, requiring PHP clients to receive an updated active treatment plan every 30 days. Clients receiving PHP are more acute and typically receive care in the CMHC multiple days a week for several hours a day. The PHP client will have changing needs as they progress through their treatment plan; therefore, updating the assessment every 30 days or sooner if the client's condition changes continues to be an important requirement for the PHP client.

While the minimum 30 day update time fame at § 485.914(d) is needed for clients receiving PHP services, we do not believe that this time frame requirement supports the needs of all CMHC clients. Clients that do not receive PHP services may be seen weekly or every 2 weeks, while others are only seen every 2–6 months for a medication follow up. Requiring an updated assessment every 30 days may not be practical for the non-PHP client, causing either additional visits or phone calls from the CMHC to the client to document ''no changes in the client's assessment''. This is not an efficient use of CMHC clinician or client time. Therefore, we propose to modify this standard at § 485.914(d)(1) to require that the CMHC update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred, and in accordance with current standards of practice. Additionally at § 485.914(d)(3), we propose to retain the minimum 30 day assessment update time frame for those clients who receive PHP services. We believe this proposed change will allow for the provider and client to choose a visit schedule that is appropriate for the client's condition and not cause extra work or time for documentation that is unnecessary. Ultimately, this proposed change may allow for greater flexibility for the provider and client, saving time for both.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on CMHCs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing

requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 OPPS/ASC proposed rule. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0091.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Mary Rossi-Coajou, USPHS, 410–786–6051.

J. Portable X-Ray Services (§§ 486.104(a) and 486.106(a))

Portable x-rays are basic radiology studies (predominately chest and extremity x-rays) performed on patients in skilled nursing facilities, residents of long term care facilities and homebound patients. Under the authority of section 1861(s)(3) of the Act, the Secretary has established the CfCs that the supplier of portable x-ray services must meet to participate in Medicare and Medicaid, and these conditions are set forth at §§ 486.100 through 486.110. The portable x-ray CfCs set forth at § 486.104 were originally published on January 10, 1969 (34 FR 388) and were redesignated on September 30, 1977 (42 FR 528260), and amended on April 12, 1988 (53 FR 12015), August 30, 1995 (60 FR 45086), and November 19, 2008 (73 FR 69942). The portable x-ray CfCs set forth at § 486.106 were originally published on January 10, 1969 (34 FR 388) and were redesignated on September 30, 1977 (42 FR 52826) and further redesignated and amended January 9, 1995 (60 FR 2326), August 30, 1995 (60 FR 45086), and November 16, 2012 (77 FR 69372). The November 2012 revision to the portable x-ray requirements allowed nurse practitioners and non-physician providers acting within their scope of practice to order portable x-ray studies. The current regulations are inconsistent with other rules governing diagnostic studies, as described later in this section of this proposed rule. In order to improve consistency, we propose changes to both § 486.104, Condition for coverage: Qualifications, orientation and health of technical personnel and § 486.106, Condition for coverage: Referral for service and preservation of records.

At § 486.104, Condition for coverage: Qualifications, orientation and health of technical personnel, the portable x-ray technologist must meet any one of four training and education requirements in § 486.104(a)(1), (2), (3), or (4). The requirement focuses on the accreditation of the school rather than the competency of the individual. In contrast, § 482.26(c)(2), referring to qualifications of radiologic technologists in hospitals, is focused on the qualifications of the individual performing services as permitted by State law. Additionally, § 410.33(c), which sets forth the personnel requirements for non-physician personnel used by an independent testing facility to perform tests, requires that testing personnel, including x-ray technologists, must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. These two other regulatory requirements that govern the same type of technologists do not have any accreditation requirements. Based on our survey findings in hospitals, which have not identified widespread patient safety or quality of care concerns related to the training and education levels of technologists, we do not believe that removing the school accreditation requirement from the portable x-ray personnel requirements would negatively impact portable x-ray patient health and safety.

We propose to remove the four training and education requirements for two reasons. First, paragraph (a)(1), and to some extent paragraph (a)(4), focus on the accreditation of the school where the technologist received training, instead of focusing on the qualifications of the technologist performing the diagnostic test. Radiologic technicians who practice in a hospital, and for whom there are no requirements to receive education and training by an accredited program, are legally allowed to perform any diagnostic imaging procedure, including computed topography scans, mammograms, sonograms, and many other procedures that are more complex and require more expertise than portable x-rays. In contrast, portable x-ray radiologic technicians typically perform basic x-rays of the limbs (hand, foot) and chest, and are limited in their duties by State scope of practice rules. For this reason we are aligning the current requirements at § 486.104(a)(1), (2), (3), and (4) with § 482.26(c)(2), which refers to qualifications of radiologic technologists in hospitals, and is focused on the qualifications of the individual performing services as permitted by State law. This change would not preclude state licensure entities and portable x-ray suppliers from establishing personnel requirements that are more stringent that the proposed Federal requirements.

Second, paragraphs (a)(2), (3), and (4) establish different personnel qualifications based on the date that a technologist received his or her education and training. We do not believe that it is efficient or necessary to have varying qualifications based simply on the date that such training was received. We propose to replace these four different qualifications with a single, streamlined qualification that focuses on the skills and abilities of the technologist. We believe that removing school accreditation requirements and simplifying the requirements will reduce regulatory burden, streamline the hiring process, and widen the pool of individuals who may be employed by portable x-ray suppliers to perform portable x-ray services, particularly those individuals who received training through the military for performing portable x-rays, as military training programs are not accredited.

Section 486.106(a)(2) contains specific requirements for the content of the order for portable x-ray services, and requires that physician or non-physician practitioners orders for portable x-ray services must be written and signed. The requirements at § 486.106(a)(2) are inconsistent with the order requirements at § 410.32, which also apply to portable x-ray suppliers, in two ways. First, the requirements at § 486.106(a)(2) have different order content requirements. Second, the requirements at § 486.106(a)(2) have the effect of limiting or precluding telephonic and electronic orders, which are often more efficient ordering methods. Section 410.32 allows for the diagnostic service to be ordered in writing, by telephone, or by secure electronic methods. Although, § 410.32 does not prescribe the form of an order. The Medicare Benefit Policy Manual (Pub. 100–02), chapter 15, section 80.6 provides additional guidance on § 410.32, and states:

''An order may be delivered via the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand delivered, mailed, or faxed to the testing facility; NOTE: No signature is required on orders for clinical diagnostic tests paid on the basis of the

clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services;

- A telephone call by the treating physician/practitioner or his or her office to the testing facility; and
- An electronic mail by the treating physician/practitioner or his or her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records. While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.

We propose to update § 486.106 (specific to portable x-ray services) to cross reference the requirements at § 410.32. We propose to retain the requirement that the portable x-ray order must include a statement on why it is necessary to perform a portable x-ray as opposed to performing the study in a facility where x-rays are more typically performed. This change would allow for portable x-ray services to be ordered in writing, by telephone, or by electronic methods. The change would also streamline the ordering process by avoiding the need to write two separate orders for the same study, one to meet the Medicare payment requirements in accordance with § 410.32 and its associated Manual guidance, and another to meet the content requirements of the regulation set forth at § 486.106. We believe the proposed change would allow for additional ordering flexibility to streamline ordering practices while maintaining ordering and documentation requirements consistent with all other diagnostic testing.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on suppliers of portable x-ray services and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork Initiative,'' we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to the RFI that was included in the CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B. Public comments in response to this RFI can be found at the following link: *https://www.regulations.gov/docket?D=CMS-2017-0092.* Public comments on the RFI can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation docket on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Sonia Swancy, 410–786–8445.

K. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Provision of Services (§ 491.9(b)(4))

Currently, § 491.9(b)(4) requires RHCs and FQHCs to have their patient care policies reviewed at least annually by the designated group of professional personnel who advise the RHC or FQHC in developing these policies (described at § 491.9(b)(2)), and reviewed as necessary by the RHC or FQHC. We propose to reduce the frequency of policy reviews. We believe the requirement to review patient care policies annually is burdensome and diverts staff from providing patient care. We propose to require the patient care policies be reviewed on a biennial basis by the group of professional personnel. Changing the review requirement from annually to every other year would not preclude the RHC or FQHC from maintaining their current annual review, if they believe it is necessary or if it is required by facility policy. We believe that this approach would allow RHCs and FQHCs to maintain their health and safety policies in such a manner as to achieve the intended outcomes for all patients. Thus, we propose to change the requirement at § 491.9(b)(4) from ''annual'' to ''biennial''.

2. Program Evaluation (§ 491.11(a))

The current requirement at § 491.11(a) requires that the RHC or FQHC carries out, or arranges for, an annual evaluation of its total program. Some RHCs and FQHCs have reported to us that this requirement is burdensome and utilizes costly staff resources. We propose to revise the current requirement at § 491.11(a) by changing the frequency of the RHC or FQHC evaluation from annually to every other year. The revised requirement would then require a biennial evaluation of its total program. Changing the program evaluation requirement from annually to every other year would not preclude the RHC or FQHC from conducting an evaluation more frequently or maintaining their current annual evaluation, if they believe it is necessary or if it is required by facility policy. Furthermore, the proposed changes would give the RHC or FQHC the flexibility to focus only on certain program areas, if they choose to do so, for the off year in-between required program evaluations. The proposed change would reduce the paperwork burden of the RHC or FQHC and allow clinicians to focus more on patient care. We believe that an evaluation of the RHC or FQHC's total program every other year is sufficient to ensure consistent quality of care, and that the change from annual to biennial would not negatively affect patient health and safety. We welcome the public's comments on these proposed changes.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on RHCs and FQHCs and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the 2017 prospective payment regulations for most provider types. We refer readers to the public comments that were submitted in response to the RFI for the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal

Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*

- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-0001.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0105-0002.*
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*
- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.*

The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: CAPT Jacqueline Leach, USPHS, 410–786–4282.

L. Emergency Preparedness for Providers and Suppliers

On September 16, 2016, we published a final rule entitled, ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' (81 FR 63860), which established national emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers (referred to collectively as ''facilities'' in the subsequent section) to plan adequately for both natural and man-made disasters and coordinate with Federal, State, tribal, regional, and local emergency preparedness systems. In that final rule, we emphasized the need for facilities to maintain access to healthcare services during emergencies, safeguard human resources, and maintain business continuity and protect physical resources. A facility's emergency preparedness program must include the following elements:

- Risk assessment and emergency planning
- Policies and procedures
- Communication plan
- Training and testing

After the publication of that final rule, we continued to review and analyze the final emergency preparedness requirements and pertinent stakeholder feedback. Upon further review, we believe that some emergency preparedness requirements could be modified or eliminated to reduce provider and supplier burden while continuing to maintain essential emergency preparedness requirements that preserve the health and safety of patients in the United States. The following proposals would simplify the emergency preparedness requirements, eliminate duplicative requirements, and/or reduce the frequency with which providers and suppliers would need to perform certain required activities. We note that the current emergency preparedness standards are similar amongst all provider and supplier types, with a few variations to account for differences in health care settings. For clarity in the discussion later in this section of this proposed rule, we often refer to the hospital regulatory citation and we include specific references to other provider or supplier types when necessary.

1. Annual Review of Emergency Preparedness Program (§§ 403.748, 416.54, 418.113, 441.184, 460.84, 482.15, 483.73, 483.475, 484.102, 485.68, 485.625, 485.727, 485.920, 486.360, 491.12, and 494.62 (a), (b), (c), and (d))

Facilities are currently required to annually review their emergency preparedness program, which includes a review of their emergency plan, policies and procedures, communication plan, and training and testing program. However, pertinent stakeholders continue to question whether an annual review of the emergency program is necessary or beneficial to the facility. In response to their comments, we are therefore proposing to change this requirement to require facilities to review their program at least every 2 years. This will increase the facility's flexibility to review their programs as they determine best fits their needs. We expect that facilities would routinely revise and update their policies and operational procedures to ensure that they are operating based on best practices. In addition, facilities should update their emergency preparedness program more frequently than every 2 years as needed (for example, if staff changes occur or lessons-learned are acquired from a real-life event or exercise).

As noted in the Emergency Preparedness final rule (81 FR 63860), ''. . . there are various infections and diseases, such as the Ebola outbreak in October, 2014, that required updates in facility assessments, policies and procedures and training of staff beyond the directly affected hospitals. The final rule requires that if a facility experiences an emergency, an analysis of the response and any revisions to the emergency plan will be made and gaps and areas for improvement should be addressed in their plans to improve the response to similar challenges for any future emergencies.''

The Assistant Secretary for Preparedness and Response (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE) located at: *https://asprtracie.hhs.gov/,* is an excellent resource for the various CMS providers and suppliers as they seek to implement the emergency preparedness requirements. TRACIE is designed to provide resources and technical assistance to healthcare system preparedness stakeholders in building a resilient healthcare system. There are numerous products and resources located within the TRACIE website that target specific provider types affected by the emergency preparedness aspects of this proposed rule. While TRACIE does not focus specifically on the requirements implemented in this proposed regulation, this is a valuable resource to aid a wide spectrum of partners with their health system emergency preparedness activities. We strongly encourage providers and suppliers to utilize TRACIE and leverage the information provided by ASPR.

2. Documentation of Cooperation Efforts (§§ 403.748(a)(4), 416.54(a)(4), 418.113(a)(4), 441.184(a)(4), 460.84(a)(4), 482.15(a)(4), 483.73(a)(4), 483.475(a)(4), 484.102(a)(4), 485.68(a)(4), 485.625(a)(4), 485.920(a)(4), 486.360(a)(4), 491.12(a)(4), and 494.62(a)(4))

Facilities are currently required to develop and maintain an emergency preparedness plan that includes a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the facilities' efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. Upon further review of this requirement, we believe that elements of this requirement are unduly burdensome on facilities. Therefore, we propose to eliminate the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and facilities' participation in collaborative and cooperative planning efforts. Facilities will still be required to include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. We believe that eliminating this documentation requirement will reduce provider and supplier burden by not requiring facilities to demonstrate that they have contacted local, tribal, regional, State, and Federal emergency preparedness officials or participated in collaborative and cooperative planning in the community, while still requiring facilities to at least include a process for cooperation and collaboration. We continue to encourage facilities to participate, when available, in community cooperative and collaborative planning efforts and execute the training and testing requirements in § 482.15 (d) for hospitals and similar parallel citations for other facilities.

3. Annual Emergency Preparedness Training Program (§§ 403.748(d)(1)(ii), 416.54(d)(1)(ii), 418.113(d)(1)(ii), 441.184(d)(1)(ii), 460.84(d)(1)(ii), 482.15(d)(1)(ii), 483.73(d)(1)(ii), 483.475(d)(1)(ii), 484.102(d)(1)(ii), 485.68(d)(1)(ii), 485.625(d)(1)(ii), 485.727(d)(1)(ii), 485.920(d)(1)(ii), 486.360(d)(1)(ii), 491.12(d)(1)(ii), and 494.62(d)(1)(ii)

Facilities are required to develop and maintain a training program that is based on the facility's emergency plan. This emergency preparedness training must be provided at least annually and a well-organized effective training program must include initial training in emergency preparedness policies and procedures. We revisited the public comments received on the Emergency Preparedness proposed rule (81 FR 63890 through 63891) and determined that requiring facilities to provide annual training may be unduly burdensome. We are therefore proposing to change this requirement to require that facilities provide training biennially or every 2 years, after facilities conduct initial training on their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated. For example, when a facility makes substantial changes to the procedures or protocols within the emergency plan, we would require additional training on the updated emergency plan. Other non-significant updates, such as revisions to the communication plan regarding contact information for staff, could be sent in company memorandum or provided to the facility's staff through other means. These proposed changes give facilities additional flexibility to determine what is appropriate for their facility's or staff's needs while maintaining adequate readiness.

4. Annual Emergency Preparedness Testing (§§ 403.748(d)(2), 416.54(d)(2), 418.113(d)(2), 441.184(d)(2), 460.84(d)(2), 482.15(d)(2), 483.73(d)(2), 483.475(d)(2), 484.102(d)(2), 485.68(d)(2), 485.625(d)(2), 485.727(d)(2), 485.920(d)(2), 486.360(d)(2), 491.12(d)(2), and 494.62(d)(2))

Facilities are currently required to conduct exercises to test the emergency plan at least annually. The facility must conduct two emergency preparedness testing exercises every year. Specifically, facilities must:

- Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the facility experiences an actual natural or-man made emergency that requires activation of the emergency plan (including their communication plan) and revision of the plan as needed), the facility is exempt from engaging in a community-based or individual, facility based full-scale exercise for 1 year following the onset of the actual event;
- Conduct an additional exercise that may include either a second full-scale exercise that is community-based or individual, facility-based or a tabletop exercise that includes a group discussion led by a facilitator.

Upon further analysis of this requirement, and taking into account stakeholder feedback, we have determined that there is also a need to clarify and revise some of the requirements included in the Emergency Preparedness final rule (81 FR 63860). We propose to clarify our intent with regard to the types of testing exercises, specifically full-scale exercises and functional exercises. As noted in the Emergency Preparedness proposed rule (78 FR 79101), a full-scale exercise is a multi-agency, multijurisdictional, multi-discipline exercise involving functional (for example, joint field office, emergency operation centers, etc.) and ''boots on the ground'' responses (for example, firefighters decontaminating mock victims). We expect facilities to engage in such comprehensive exercises with coordination across the public health system and local geographic area, if possible. Moreover, a functional exercise examines or validates the coordination, command, and control between various multiagency coordination centers (for example, emergency operation center, joint field office, etc.). A functional exercise does not involve any ''boots on the ground'' (that is, first responders or emergency officials responding to an incident in real time). The term ''functional exercise'' more accurately reflects our intentions for the testing requirement in the Emergency Preparedness final rule (81 FR 63860). We believe that there are opportunities to reduce the burden for inpatient and outpatient providers to meet the testing requirement.

For providers of inpatient services, we propose to expand the testing requirement options such that one of the two annually required testing exercises may be an exercise of their choice, which may include one community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. As indicated in the Emergency

Preparedness proposed rule, ''A workshop resembles a seminar, but is employed to build specific products, such as a draft plan or policy (for example, a Training and Exercise Plan Workshop is used to develop a Multiyear Training and Exercise Plan)'' (78 FR 79101). Providers of inpatient services include RNHCIs, inpatient hospice facilities, Psychiatric Residential Treatment Facilities (PRTFs), hospitals, long-term care facilities (LTCFs), ICFs/IIDs, and CAHs. We believe this will allow greater flexibility for inpatient providers to meet this requirement. We note that although RNHCIs provide inpatient services, we have determined that changing their existing requirements to make them consistent with this proposed provision will be unduly burdensome as they are currently required to conduct a paper-based, tabletop exercise at least annually.

For providers of outpatient services, we believe that conducting two testing exercises per year is overly burdensome as these providers do not provide the same level of acuity or inpatient services for their patients. Therefore, we propose to require that providers of outpatient services conduct only one testing exercise per year. Furthermore, we propose to require that these providers participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year. In the opposite years, we propose to allow these providers to conduct the testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. Providers of outpatient services include ASCs, freestanding/home-based hospice, Program for the All-Inclusive Care for the Elderly (PACE), HHAs, CORFs, Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), CMHCs, Organ Procurement Organizations (OPOs), RHCs, FQHCs, and ESRD facilities. Due to the nature of services provided by OPOs we propose to require that they have the option of providing either a tabletop exercise or workshop every year.

Lastly, we propose to clarify the testing requirement exemption by noting that if a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event. A facility's communication plan is part of their emergency plan, as is coordination with other community emergency preparedness officials (for example, emergency management and public health), and we expect that these elements, along with the completion of a corrective action plan, are part of the activation of their emergency plan.

We seek to reduce burdens for health care providers and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction in future rulemaking. Specifically, we are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on all Medicare and Medicaid participating providers and suppliers mentioned in this section and create cost savings, while also preserving quality of care and patient health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. We also note that such suggestions could include or expand upon comments submitted in response to RFIs that were included in the following 2017 payment regulations:

- End-Stage Renal Disease Prospective Payment System and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program found at *https://www.regulations.gov/docket?D=CMS-2017-0084.*
- CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements found at *https://www.regulations.gov/docket?D=CMS-2017-0100.*
- FY 2018 Hospice Wage Index and Payment Rate Update and Hospice Quality found at *https://www.regulations.gov/document?D=CMS-2017-0062-000.*
- FY 2018 Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System RFI, found at *https://www.regulations.gov/docket?D=CMS-2017-0055.*
- CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates found at *https://www.regulations.gov/docket?D=CMS-2017-0091.*
- FY 2018 Inpatient Rehabilitation Facility Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0059-0002.*
- FY 2018 Inpatient Psychiatric Facilities Prospective Payment System found at *https://www.regulations.gov/document?D=CMS-2017-0105-0002.*
- CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B found at *https://www.regulations.gov/docket?D=CMS-2017-0092.*
- FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities found at *https://www.regulations.gov/document?D=CMS-2017-0060-0002.*

Public comments on the RFIs can be found by searching for the terms ''RFI'' or ''request for information'' in the aforementioned 2017 payment regulation dockets on *www.regulations.gov.* The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

Contact: Kianna Banks, 410–786–3498.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-

required issues for the following information collection requirements (ICRs).

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2016/may/oes_nat.htm*). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead costs (calculated at 100 percent of salary), and the adjusted hourly wage.

NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hour)	Fringe benefit ($/hour)	Adjusted hourly wage ($/hour)
Healthcare Support Worker	31–9099	$18.13	$18.13	$36
Physicians and Surgeons	29–1060	101.04	101.04	202
Physicians and Surgeons, All Other	29–1069	98.83	98.83	198
Physicians, Psychiatrists	29–1066	94.26	94.26	189
Surgeons	29–1067	121.59	121.59	243
Registered Nurse (RN—Quality Improvement, Home Care Coordinator, HealthCare Trainer, Quality Assurance Nurse, QAPI Nurse Coordinator, Infection Control Nurse Coordinator, Psychiatric RN)	29–1141	34.70	34.70	69
Medical Secretary (Clerical, Administrative Assistant)	43–6013	16.85	16.85	34
Administrative Services Manager (Facility Director)	11–3011	47.56	47.56	96
Management Occupations (Director, Community Relations Manager, Administrator)	11–0000	56.74	56.74	114
Pharmacist	29–1051	57.82	57.82	115
Medical and Health Services Manager (Administrator, Transplant Program Senior Administrator/Hospital Administrator/Medical and Health Services Managers, Program Director, Risk Management Director. QAPI Director, Organ Procurement Coordinator, Nurse manager, Director of Nursing, Nursing care facilities/skilled nursing facilities)	11–9111	52.58	52.58	105
Managers, All Others(Administrator)	11–9199	53.92	53.92	108
*Activities Specialist (Recreational Therapists, Nursing Care Facilities/SNFs)	29–1125	19.92	19.92	40
Internists (Medical Director, General Physician	29–1063	97.04	97.04	194
Family and General Practitioner (Medical Director)	29–1062	96.54	96.54	194
Physical Therapist (Director of Rehab)	29–1123	41.93	41.93	84
Healthcare Social Worker (Social Worker)	21–1022	26.69	26.69	53
Mental Health and Substance Abuse Social Worker (Social Worker)	21–1023	23.02	23.02	46
Nurse Practitioner (Clinician, Nurse Practitioner Outpatient Care Center)	29–1171	50.30	50.30	101
Mental Health Counselor	21–1014	22.14	22.14	44
Physician Assistant	29–1071	49.08	49.08	98
Licensed Practical and Licensed Vocational Nurses (Director of Nursing)	29–2061	21.56	21.56	44
First Line Supervisors of Office and Administrative Support Workers (Office Manager)	43–1011	27.83	27.83	56
Office Clerks, General (Clerical staff)	43–9061	15.87	15.87	32
Secretaries and Administrative Assistants (Clerical staff)	43–6010	19.39	19.39	38
Chief Executive	11–1011	93.44	93.44	186

*Salary information used is for Nursing Care Facility/SNF industry. As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. ICRs Regarding RNHCI Discharge Planning (§ 403.736(a) and (b))

Section 403.736 will reduce the extensive requirements for an RNHCI to coordinate with other medical providers for post-RNHCI care. The discharge evaluation must include an assessment of a patient's capacity for self-care and information regarding the care once the patient leaves the facility. The nursing staff would need to prepare the patient and/or their caregiver for discharge. Most patients are discharged to home or to another facility that adheres to the same religious tenets. Although all patients must have a discharge planning evaluation, not all patients require a discharge plan. Based on recent claims data, there was a combined annual total of 619 beneficiaries that stayed in the 18 facilities.

We estimate that the time currently required to develop and document discharge plans and activities is 1,238 burden hours (2 hours for each of the 619 beneficiaries discharged) and that it would be reduced by half. Of the approximately 619 annual discharges, we estimate that a RNHCIs burden would be reduced to one hour for each discharged individual. A RNHCI would not need to develop a discharge plan that includes medical care once a patient leaves the RNHCI because doing so would not be in keeping with the religious tenets of the patients they serve. We estimate that the healthcare support worker responsible for a patients discharge plan is paid at mean wage of $36, including 100 percent for fringe and overhead costs. Based on our experience with RNHCIs, we estimate that it would take 1 hour to develop the proposed discharge instructions and discuss them with the patient and/or caregiver. We estimate a total of 619 annual discharges from RNHCIs at a savings of $36 per discharge for a total savings of $22,284 ($36 × 619 hours).

C. ICRs Regarding ASC Governing Body and Management (§ 416.41(b)(3)(i) and (ii))

We propose to eliminate the requirements at § 416.41(b)(3) that states the ASC must have a written transfer agreement with a hospital or ensure all physicians performing surgery in the ASC have admitting privileges at a local hospital that meets CMS hospitalization requirements. All ASCs easily meet this requirement and have established a relationship with their local hospital and obtained an agreement as usual and customary practice for running an ASC with the exception of approximately twenty ASCs that have difficult relationships with their local hospitals. The savings would not be significant, however, it does affect the 20 ASCs by removing the requirement. The current information collection request for the ASC rules (OMB control number 0938–1071) does not address any potential burden associated with this requirement. We believe that having and maintaining written agreements is standard practice. Therefore, removing this requirement would not alter the current information collection burden for ASCs.

D. ICR Regarding ASC Medical Records (§ 416.47(b)(2))

We propose to revise § 416.47(b)(2) by adding the phrase ''(as applicable)'' to the significant medical history and results of physical examination requirement of documents that must be included in the medical record in order to conform to the changes that we are proposing to the mandatory medical history and physical examination requirement. There are no collection of information requirements associated with this proposed change because maintaining a medical record for each patient is a usual and customary practice in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

E. ICRs Regarding ASC Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4))

At § 416.52 we propose to replace the requirement that every patient have a comprehensive medical history and physical examination (H&P) within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. The burden associated with this requirement would be the time and effort necessary to create new policies for when, and whether, to require some form of history and physical that would require pre-operative examination and testing, and on what time schedule. The current information collection request for the ASC rules (OMB control number 0938–1071) does not account for any information collection related burden associated with the comprehensive H&P requirement. We assume that creating these policies (which could leave such decisions to the surgeon's discretion in most or all cases) would require 10 hours of physician time, 10 hours of RN time, and 10 hours of clerical time, at the preceding hourly rates, for a total of 30 hours per facility. This would be a one-time cost of $3,440 per facility ([10 × $243] + [10 × $69] + [10 × $32]), and $19.1 million for all 5,557 facilities. Therefore, this proposed requirement would increase the information collection related burden by $19.1 million and 166,710 hours (30 hours × 5,557 facilities) on a one-time basis for all ASCs. The information collection request will be revised to account for the additional burden.

F. ICRs Regarding Hospice Aide and Homemaker Services (§ 418.76)

At § 418.76(a) we propose to defer to State training and competency requirements, where they exist, for hospice aides. The information collection request for the hospice requirements (OMB control number 0938–1067) is currently under review at OMB. It estimates that a hospice would spend 5 minutes per newly hired hospice aide to document verification that an aide meets the required training and competency requirements, for a total of 372 annual burden hours for all hospices at a cost of $11,540. This proposed change to the actual training and competency requirements would not alter the requirement to document the fact that a hospice aide meets one of the training and competency requirements set forth in the rule; therefore there would be no change to the existing collection of information estimates because the estimates relate to the unchanged documentation requirements rather than the actual training and competency requirements that would be revised by this proposed change.

G. ICRs Regarding Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§ 418.106(a) and (e)(2)(i))

At § 418.106(a) we propose to remove the requirement that a hospice ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. The information collection request for the hospice requirements (OMB control number 0938–1067, currently under review at OMB) states that the burden associated with this requirement is the time necessary to document the results of this consultation in each patient's clinical record. In the information collection request we assumed that an average hospice would confer with a pharmacist, and that the pharmacist would document the results of his/her consultation. We estimated that it requires 5 minutes to document the initial review of a patient's drug and biologicals. Additionally, we estimated that it requires 5 minutes of the pharmacist's time to document a review of updates to the patient's drug profile. Based on a 17 day median length of service, we assumed that each patient would likely receive one update to their plans of care. At an average hourly rate of $115 for a pharmacist, we estimated that it would cost a hospice $19 per patient ($115 × [5 minutes for initial + 5 minutes for 1 update]) and an annual cost of $6,764 ($19 × 356 patients). The total annual burden hours for all hospices was estimated to be 264,588 hours (1,587,527 patients × .1666 hour per patient), and the total annual burden cost for all hospices was estimated to be $30,163,013 ($19 per patient × 1,587,527 patients). Therefore, removing the requirement that a hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management would result in a burden reduction of 264,588 hours and $30,163,013.

We assume that, upon implementation of the proposed change to allow hospices to provide information regarding the safe maintenance and disposal of controlled drugs in a more user-friendly manner, hospices would develop understandable instructions in layperson terms to replace the copy of the policies and procedures that is currently provided. While the instructions could be created in any number of formats, such as a slide show, video, podcast, or pictograph, for purposes of our analysis we assume that hospices would create written instructions. We estimate that a hospice would use 1 hour of administrator time to develop a new form at $105 per hour. For all 4,602 hospices, the total initial cost would be $483,210.

The information collection request will be revised and sent to OMB.

H. ICRs Regarding Hospices That Provide Hospice Care to Residents of a SNF/NF or ICF/IID (§ 418.112(c)(10) and (f))

At § 418.112(f) we propose to allow hospices and long term care facilities the additional flexibility to negotiate the format and schedule for orienting long term care facility staff regarding certain hospice-specific information. A hospice and SNF/NF or ICF/IID must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospices and the SNF/NF or ICF/IID prior to the provision of hospice care services. The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. As stated in the hospice information collection request (OMB control number 0938–1067, currently under review at OMB), the use of this type of written agreement is a usual and customary business practice and the associated burden is exempt from the PRA under the implementing regulations at 5 CFR 1320.3(b)(2). However, updating the written agreement to address this new requirement would not constitute a usual and customary business practice; therefore, we believe that a one-time burden to update the written agreement would be imposed by this change. For purposes of this analysis only, we estimate that each hospice would use 8 hours of administrator time to revise the existing written agreement. At a cost of $105 per hour for an administrator to complete this task, we estimate that the onetime cost per hospice would be $840. For all hospices the onetime cost would be $3,865,680 (4,602 hospices × $840) for 36,816 hours (4,602 hospices × 8 hours). The information collection request will be revised to account for this one time increase in burden and sent to OMB.

I. ICRs Regarding Hospital Quality Assessment and Performance Improvement (QAPI) Program (§ 482.21)

We propose a new standard at § 482.21(f), ''Unified and integrated QAPI program for multi-hospital systems''. We would allow that for a hospital that is part of a hospital system consisting of two or more separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, the system governing body could elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that: the unified and integrated QAPI program was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and the unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

As stated in the information collection request for the hospital requirements (OMB control number 0938–0328), which is in the process of being reinstated, we estimate that the burden associated with updating and, in some instances, writing new hospital policies directly related to patient care would be an average of eight (8) hours annually for each member of hospital staff involved in the specific patient care policies addressed.

Patient care policy development (and revision) by hospital medical staff is essential to patient health and safety because it provides the framework within which all patient care services are furnished. Thus, we have included the involvement of a physician at approximately $1,584 annually (8 burden hours × $198), a QAPI nurse coordinator at $552 annually (8 burden hours × $69), and a medical secretary at $272 annually (8 burden hours × $34).

We estimate the necessary policy changes needed to comply with the requirements proposed in this rule would cost $2,408 per year ($1,584 + $552 + $272) for each of the 424 hospital systems that would be eligible to do so and that would choose to exercise this option. Therefore, the total annual cost for all eligible hospital systems to meet these information collection requirements would be approximately $1 million.

J. ICRs Regarding Hospital Medical Staff, Medical Records Services, and Surgical Services (§§ 482.22, 482.24, and 482.51)

At § 416.52 we propose to replace the requirement that every patient have a comprehensive H&P within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. As discussed in ''Provisions of the Proposed Regulations,'' section II.D.2 of this proposed rule, there is a similar regulatory requirement for hospital outpatient surgery. Based on the substantial similarity between these two service settings, we propose, through the revisions to §§ 482.22, 482.24, and 482.51 discussed in section II.D.2, to provide an exception to these requirements for outpatient surgery in hospitals.

As stated in the information collection request for the hospital requirements (OMB control number 0938–0328), which is in the process of being reinstated, we estimate that the burden associated with updating and, in some instances, writing new hospital policies directly related to patient care would be an average of eight (8) hours annually for each member of hospital staff involved in the specific patient care policies addressed.

Patient care policy development (and revision) by hospital medical staff is essential to patient health and safety because it provides the framework within which all patient care services are furnished. Thus, we have included the involvement of a physician at approximately $1,584 annually (8 burden hours × $198), a nurse coordinator at $552 annually (8 burden hours × $69), and a medical secretary at $272 annually (8 burden hours × $34).

We estimate that the necessary policy changes needed to comply with the requirements proposed in this rule would cost $2,408 per year ($1,584 + $552 + $272) for each of the 5,031 hospitals that might choose to exercise this option. Therefore, the total annual cost for all hospitals to meet these information collection requirements would be approximately $12.1 million.

K. ICRs Regarding Hospital Medical Staff: Autopsies (§ 482.22)(d))

We propose to remove the requirement at § 482.22(d), which recommends that a hospital's medical staff attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Hospitals are further required to define a mechanism for documenting permission to perform an autopsy, and they must have a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. Since more detailed, specific requirements regarding medical-legal investigations and autopsies for

hospitals are covered by the individual State laws in which the hospital is located, there are no collection of information requirements associated with this proposed change.

L. ICRs Regarding Hospital Infection Control (§ 482.42)

We propose a new standard at § 482.42(c), ''Unified and integrated infection control program for multi-hospital systems.'' Like the proposed requirements for a unified and integrated QAPI program, the proposed standard for infection control would allow that for a hospital that is part of a hospital system consisting of multiple separately certified hospitals subject to a system governing body legally responsible for the conduct of each hospital, such system governing body could elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision was in accordance with all applicable State and local laws. The system governing body would be responsible and accountable for ensuring that each of its separately certified hospitals met all of the requirements of this section. Each separately certified hospital subject to the system governing body would have to demonstrate that the unified and integrated infection control program: (1) Was established in a manner that took into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; (2) established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, were given due consideration; (3) had mechanisms in place to ensure that issues localized to particular hospitals were duly considered and addressed; and (4) has designated a qualified individual(s) with expertise in infection prevention and control at the hospital to be responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control, and for providing infection prevention education and training to hospital staff.

As stated in the information collection request for the hospital requirements (OMB control number 0938–0328), which is in the process of being reinstated, we estimate that the burden associated with updating and, in some instances, writing new hospital policies directly related to patient care would be an average of eight (8) hours annually for each member of hospital staff involved in the specific patient care policies addressed.

Patient care policy development (and revision) by hospital medical staff is essential to patient health and safety because it provides the framework within which all patient care services are furnished. Thus, we have included the involvement of a physician at approximately $1,584 annually (8 burden hours × $198), an infection control nurse coordinator at $552 annually (8 burden hours × $69), and a medical secretary at $272 annually (8 burden hours × $34).

We estimate the necessary policy changes needed to comply with the requirements proposed in this rule would cost $2,408 per year ($1,584 + $552 + $288) for each of the 424 hospital systems that would be eligible to do so and that would elect to exercise this option. Therefore, the total annual cost for all eligible hospital systems to meet these information collection requirements would be approximately $1 million.

M. ICRs Regarding Special Requirements for Hospital Providers of Long-Term Care Services (''Swing-Beds'') (§ 482.58(b)(1), (4), (5), and (8), and Identical CAH requirements: § 485.645(d)(1), (4), (5), and (8))

At §§ 482.58(b)(1) and 485.645(d)(1) (cross-referenced long-term care requirement at § 483.10(f)(9)) we propose to remove the requirement for hospital and CAH swing-bed providers to provide the right for patients to choose to or refuse to perform services for the facility and if they so choose; (a) document in the resident's plan of care, (b) noting whether the services are voluntary or paid and (c) provide wages for the work being performed given the location quality, and quantity of work requiring comparable skills. We believe this requirement is unduly burdensome as we do not expect patient's receiving hospital or CAH swing-bed services have an average length of stay long enough to be positively impacted by providing services to the facility. We assume that each of the hospital swing-bed providers (478 hospitals) and CAH swing-bed providers (1,246 CAHs) has an activities specialist employed at $40 per hour who would oversee the residents who have chosen to perform services for the facility, and document and update the plan of care accordingly. We believe that given the limited budget of most rural providers, services are being provided to the CAH on a voluntary basis and that these providers are not compensating patients for providing these services. The current regulatory burden for compliance with this requirement is approximately $29 million for all hospital and CAH swing-bed providers, or $16,821 per hospital or CAH swing-bed provider (1,724 hospital and CAH swing-bed providers × $40 an hour for an activities specialist × 8 hours per week × 52 weeks per year), which are the cost savings to the providers as a result of the removal of this requirement.

At § 482.58(b)(4) (and § 485.645(d)(4)) (cross-referenced long-term care requirement at § 483.24(c)), we propose to remove the requirement for hospital and CAH swing-bed providers to provide an ongoing activity program that is directed by a qualified therapeutic recreation specialist or an activities professional who meets certain requirements as listed at § 483.24(c)(2). We assume that each of the hospital swing-bed providers (478 hospitals) and CAH swing-bed providers (1,246 CAHs) has an activities specialist employed at least part time at $40 per hour. CAHs are required to provide activity services by either a qualified individual who meet the requirements of § 483.24(c)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy. For the purpose of this analysis, we assume that the cost of each would be the same due to the rural location of CAHs. The current regulatory burden for compliance with this requirement is based on the activities specialist organizing, overseeing, and scheduling the activity. The cost savings as a result of the removal of this requirement are approximately $72 million for all hospital and CAH swing-bed providers, or $41,800 per hospital or CAH swing-bed provider (1,724 hospital and CAH swing-bed providers × $40 an hour for an activities specialist × 1,040 hours per year) which are the cost savings to the providers. Our analysis assumes that the reduced staffing is largely for part-time work assignment (1,040 hours annually) at hospital and CAH swing-bed providers. It is likely that many of the actual persons holding these positions were full-time workers not devoted solely to recreational therapy, whose hours will simply be reassigned to other functions, with providers ultimately saving these full-time equivalent hours through ripple effects on an even wider range of staffing functions through turnover over time.

We propose to remove the requirement at §§ 482.58(b)(5) and 485.645(d)(5) (cross-referenced long-

term care requirement at § 483.70(p) for hospital and CAH swing-bed providers to employ a qualified social worker on a full-time basis if the facility has more than 120 beds. Given that this provision is not applicable to either provider type due to the regulatory requirements for each, it does not impose a burden upon hospitals and as such, its removal would not result in a savings of economic burden hours or dollars.

At §§ 482.58(b)(8) and 485.645(d)(8) (cross-referenced long-term care requirement at § 483.55(a)(1)) we propose to remove the requirement for hospital and CAH swing-bed providers to assist in obtaining routine and 24-hour emergency dental care to its residents.

Under the current CoPs, hospitals and CAHs are currently required to address the emergent dental care needs of their patients at § 482.12(f)(2) for hospitals, and at § 485.618 (emergency services) for CAHs. As a result, we have calculated the burden associated with the provision of routine dental care for hospital and swing-bed patients. The American Dental Association recommends annual dental checkups for routine dental care for adults over 60 years of age. With an average length of stay in a hospital or CAH swing-bed of 1–2 weeks and an average daily census of 2 patients, we assume that 1 patient receiving swing-bed services will require routine dental services per month. While a dentist and dental hygienist provide the dental services, Medicare is billed for the provision of these services. The costs to the provider are related to the nursing activities associated with the patient receiving the dental services. The current regulatory burden for compliance with this requirement is approximately $2.9 million for all hospital and CAH swing-bed providers, or $1,682 per hospital or CAH swing-bed provider (1,724 hospital and CAH swing-bed providers × $69 an hour for a RN × 24 hours per year), which are the cost savings to the providers as a result of the removal of this requirement. The information collection requests will be revised and sent to OMB for approval (OMB control number 0938–0328 for hospitals and 0938–1043 for CAHs).

N. ICRs Regarding Special Requirements for Psychiatric Hospitals (§ 482.61(d))

At § 482.61(d) we propose to clarify the requirement allowing non-physician practitioners to document progress notes in accordance with State laws and scope of practice requirements. We believe this would apportion the burden associated with having MDs/DOs document their progress notes in psychiatric hospitals with non-physician practitioners and will decrease costs associated with this activity. In accordance with the information collection request for the hospital requirements, which includes the special requirements for psychiatric hospitals (OMB control number 0938–0328), no burden is associated with recordkeeping, as the documentation and maintenance of medical records is usual and customary. However, since we believe that clarification of the intent of the regulation is necessary and will result in non-physician practitioners (specifically physician assistants, nurse practitioners, psychologists, and clinical nurse specialists) documenting the progress notes for patients receiving services in psychiatric hospitals, we are attributing ICR burden savings for this provision. For purposes of this analysis only, we estimate that MDs/DOs spend approximately 30 minutes documenting progress notes in psychiatric hospitals. We estimate that 33 percent of this time would be covered by non-physician practitioners. Of the 5,031 Medicare participating hospitals, 574 (or 11 percent) are psychiatric hospitals. According to AHA, there were 35,061,292 inpatient hospital stays in 2015, and an estimated 11 percent of these stays were at psychiatric hospitals. The proposed change would result in a savings of $62.4 million (3,856,742 psychiatric hospital stays × 0.5 hours of physician/psychiatrist time × $98 per hourly wage difference between physicians/psychiatrists ($198) and non-physician practitioners ($100, the average wage between nurse practitioners and physician assistants) × 33 percent of physician time spent writing progress notes covered by non-physician practitioners). This savings is equivalent to $108,647 per psychiatric hospital per year.

O. ICRs Regarding Special Requirement for Transplant Centers and Definitions (§§ 482.68 and 482.70)

We are proposing a nomenclature change at part 482 and the transplant center regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61. Because this change would update the terminology used in the regulations to conform to the terminology that is widely used and understood within the transplant community, there are no collection of information requirements associated with this proposal.

P. ICRs Regarding Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers (§ 482.82)

Section 482.82 requires that, except as specified in § 488.61, transplant centers must meet all the data submission, clinical experience, and outcome requirements to be re-approved for Medicare participation. Section 482.82(a) requires that no later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donors) it has performed over the 3 year approval period. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow up, and living donor registration and follow up. Furthermore, § 482.82(b) requires transplant centers to perform an average of 10 transplants per year during the prior 3 years and § 482.82(c) requires transplant centers to meet the outcome requirements for Medicare re-approval. The burden associated with this requirement would be the time it would take a transplant program to submit the required information. However, as required by §§ 482.72 and 482.45(b), a hospital in which a transplant program is located, must belong to the OPTN, and the OPTN requires that these hospitals submit this data to the OPTN. Therefore, we believe that the requirements under § 482.82 do not impose an additional burden on transplant programs because all Medicare participating transplant programs are already submitting this information to the OPTN. Removing these requirements will have no additional collection of information burden on transplant programs. We describe additional life-saving benefits that result from the removal of this proposal in the subsequent RIA section.

Q. ICRs Regarding Special Procedures for Approval and Re-Approval of Organ Transplant Centers (§ 488.61(f) Through (h))

Section 488.61(f) through (h) sets out the process for our consideration of a transplant center's mitigating factors in initial approval and re-approval surveys, certifications, and enforcement actions for transplant centers. The provisions also set out definitions and rules for transplant systems improvement agreements. We are proposing to remove the requirements at § 488.61(f) through (h) for mitigating

factors and transplant systems improvement agreements for the re-approval process for transplant centers. This change is complementary to the proposed removal of § 482.82, described previously. The information collection request (OMB Control Number 0938–1069) does not account for any information collection related burden associated with the requirements in § 488.61(f) through (h) for the re-approval process. Therefore, we estimate that the requirements under § 488.61(f) would require a transplant program to write and submit the initial formal notice of the program's intent to seek mitigating factors re-approval, and write and submit a request for consideration of mitigating factors (which would include all of the content listed in § 488.61(f)(2)). We estimate that this would take a medical director, a transplant center senior administrator, and a hospital administrator approximately 5 hours, or 2 hours for the medical director and the transplant program senior administrator and 1 hour for the hospital administrator, to complete and submit these mitigating factors for re-approval, as described in Table 2.

TABLE 2—ANNUAL BURDEN HOURS AND COST FOR TRANSPLANT PROGRAMS TO SUBMIT MITIGATING FACTORS FOR RE-APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$194	2	$388
Transplant Program Senior Administrator	105	2	210
Hospital Administrator	105	1	105
Totals		5	703

In total, we estimate that an average of 14 programs would submit mitigating factors annually. Thus, for those 14 programs we estimate that it would require 70 burden hours (5 burden hours × 14 programs) at a cost of $9,842 ($703 × 14 programs). In the context of this proposed rule, removing this requirement would yield an estimated savings to transplant programs of 5 burden hours each and a total of 70 burden hours for all 14 programs, with a total cost savings of $9,842.

In addition, we estimate that the transplant hospital in conjunction with the transplant program that is located in the hospital, would submit mitigating factors and then would also enter into systems improvement agreements, as described under § 488.61(h) annually. This would require the hospital to enter into a binding agreement with CMS to allow the program additional time to achieve compliance with the CoPs. The agreement would require hospitals to complete certain tasks as listed and described in § 488.61(h)(1), which include (but are not limited to): Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients and financial assistance to defray the out-of-pocket costs of copayments and testing expenses for any wait-listed individual who wishes to be listed with another program, an external independent peer review team that conducts an onsite assessment of the program, an action plan that addresses systemic quality improvements and is updated after the onsite peer review, an onsite consultant who provides services for 8 days per month on average for the duration of the agreement, a comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs, amongst other requirements listed in § 488.61(h)(1)(i) through (x). We estimate that this would take a medical director, a transplant program senior administrator, a hospital administrator, and an administrative assistant approximately 14 hours, or 4 hours for the medical director, transplant program senior administrator, and an administrative assistant, and 2 hours for the hospital administrator to complete these activities (including notifying patients about the degree of noncompliance by mail and organizing and completing the other tasks listed in § 488.61(h)(1) as required by the terms in the systems improvement agreement), as described in Table 3.

TABLE 3—ANNUAL BURDEN HOURS AND COST FOR TRANSPLANT PROGRAMS TO ENTER INTO A SYSTEMS IMPROVEMENT AGREEMENT FOR RE-APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$194	4	$776
Transplant Program Senior Administrator	105	4	420
Hospital Administrator	105	2	210
Administrative Assistant	34	4	136
Totals		14	1,542

In total, we estimate that an average of 14 programs will submit mitigating factors annually. Thus, for those 14 programs we estimate that it would require 196 burden hours (14 burden hours × 14 programs) at a cost of $21,588 ($1,542 × 14 transplant programs). In the context of this proposed rule, removing this requirement would yield an estimated savings to transplant programs of 14 burden hours each and a total of 196 burden hours for all 14 programs, with a total cost savings of $21,588.

R. ICRs Regarding HHA Home Health Aide Services (§ 484.80(h)(3))

We propose to eliminate the requirement at § 484.80(h)(3) that the HHA conduct a full competency evaluation of deficient home health

aides, and replace it with a requirement to retrain the aide regarding the identified deficient skill(s) and require the aide to complete a competency evaluation related only to those skills. The content of an aide competency examination does not have an associated collection of information requirement. Therefore, this proposed change would neither impose nor remove any collection of information burdens.

S. ICRs Regarding HHA Clinical Records (§ 484.110(e))

We propose to remove the requirement at § 484.110(e) related to providing a requested copy of information contained in the clinical record at the next home visit, while retaining the requirement to provide the record within 4 business days. As stated in the January 2017 HHA CoP final rule (82 FR 4568 and 4575), we believe that providing such information to patients is a usual and customary practice that does not impose a burden upon HHAs and would not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). As such, removing the ''next home visit'' timeframe requirement would not result in a savings of burden hours or dollars.

T. ICRs Regarding CORF Utilization Review Plan (§ 485.66)

We propose to reduce the required frequency in which CORFs would be required to complete a ''utilization review plan'' from quarterly to annually. Changing from a quarterly implementation of the utilization review plan to an annual implementation would reduce the current documentation requirements (OMB control number 0938–1091) on CORFs by 75 percent each year. For the purposes of our analysis, we estimate that it would take a CORF approximately 8 hours for administrative, clinical and clerical staff to review and evaluate the necessary and efficient use of services provided by the facility on a quarterly basis, for a total of 32 hours per year per CORF and 6,016 hours for all 188 CORFs. In a 1-year period, we estimate a savings of $1,644 per facility ($548 × 3 quarters), and a combined total savings of $309,072 for all CORFs ($1644 × 188 CORFs). We will submit the revised information collection request to OMB for approval.

TABLE 4—CORF—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per CORF *	Burden hours per CORF	Cost estimate per CORF
Administrator	$105	2	$210
Clerical Staff	32	2	64
Physical Therapist	84	2	168
Social Worker	53	2	106
Total	274	8	548

* Includes 100% fringe benefits & overhead costs.

U. ICRs Regarding CAH Organizational Structure (§ 485.627(b)(1))

As of May 2017, there were 1,343 CAHs that are certified by Medicare. Our proposed revision of the CAH disclosure requirements imposed on CAHs would remove the requirement for CAHs to disclose to CMS its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with 42 CFR part 420, subpart C. While we estimate that these changes occur at 2 CAHs per year on average between all 1,343 CAHs, with the vast majority not experiencing any such changes throughout the lifetime of the CAH, each CAH is still required to review the duplicative documentation. In accordance with *Medicare Program; Criteria and Standards for Evaluating Regional Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); Final Rule and Request for Comments* (57 FR 2790, June 18, 1992), the burden associated with this requirement is 1-hour per facility. As a result, this proposal will save all CAHs an estimated $141,000 and will save each CAH $105 (1-burden hour for an administrator at $105 per hour × 1,343 CAHs). We will submit the revised information collection request to OMB for approval (OMB control number 0938–0328).

V. ICRs Regarding CAH Provision of Services (§ 485.635(a)(4))

Section 485.635(a)(4) requires CAHs to conduct an annual review of all its policies and procedures. Based on feedback from stakeholders, the prescriptive annual schedule is burdensome or, in some situations, ineffective. Our proposed revision of the patient care policies requirements imposed on CAHs would reduce the frequency that is currently required for CAHs to perform a review of all their policies and procedures. We propose that a change from an annual review to a biennial review would reduce the burden on CAHs by half in a given period of time. For the purposes of our analysis, we estimate that it would take a CAH approximately 16 hours for administrative and clinical staff to review and make changes to policies and procedures annually. In a 2-year period, we estimate a savings of $1,956.10 per facility, and a combined total savings of $2.6 million for CAHs ($1,956.10 × 1,343 CAHs).

We estimate that the CAH staff time and associated costs would be assigned to a biennial review as shown in Table 5.

TABLE 5—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per CAH	Burden hours per CAH	Cost estimate per CAH
Administrator	$186.88	4	$747.52
Clerical staff	38.78	3	116.34
Registered Nurse	69.40	3	208.20

TABLE 5—HOURLY WAGES AND BURDEN HOURS—Continued

Position	Hourly wage per CAH	Burden hours per CAH	Cost estimate per CAH
Nurse practitioner	100.60	3	301.80
Physician	194.08	3	582.24
Totals	589.74	16	1,956.10

W. ICRs Regarding Special Requirements for CAH Providers of Long-Term Care Services (''Swing-Beds'') (§ 485.645(d)(1), (4), (5) and (8))

We have included the discussion of the ICRs regarding special requirements for CAH providers of long-term care services in the discussion of the ICRs regarding special requirements for hospital providers of long-term care services which can be found under section L of this part.

X. ICRs Regarding CMHCs (§ 485.914(d))

Section 485.914(d)(1) requires each CMHC to update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), no less frequently than every 30 days. We propose to modify the requirement at § 485.914(d) to remove the 30-day assessment update time frame for those clients who do not receive PHP services. Instead of a fixed 30-day time frame, assessment updates would be completed when changes in the client's status, responses to treatment, or goal achievement have occurred, and in accordance with current standards of practice. The burden associated with these requirements is the time required to record an updated assessment. The current information collection request (OMB Control number 0938–1245) does not account for any information collected related to the burden associated with updating the comprehensive assessment requirement. While in the past we believed that this is considered usual and customary practice, recent comments from the CMHC provider community, submitted in response to CMS' solicitation for public comments pertaining to burden reduction suggestions, stated that it is not usual and customary to update assessments for non-PHP clients on a 30 day schedule as required by the CMHC regulations. The commenters stated that the 30 day requirement was overly burdensome, and suggested that the CMHC assessment update requirement should more closely align with the patient-oriented approach of other entities that govern CMHC operations. Upon further consideration, we agreed with the commenter that the 30 day requirement does, in fact, impose a burden and is not usual and customary practice. Therefore, removing this requirement would reduce information collection burden for CMHCs.

Under the current 30-day time frame requirement, each client receives an updated assessment 12 times per year. We estimate that, in accordance with the proposed need-based assessment update requirements, each non-PHP client would receive 2 assessment updates in a year. Therefore, we estimate that this change would reduce the burden of 10 assessments per client, per year.

As of August 2017 there are 52 Medicare participating CMHCs serving 3,122 Medicare beneficiaries and an estimated 2,080 non-Medicare clients, for an average of 100 clients per CMHC. In order to develop the estimated number of non-Medicare clients we divided the total number of Medicare beneficiaries who received partial hospitalization services by the total number of Medicare-participating CMHCs to establish the average number of Medicare beneficiaries per CMHC. This resulted in 60 beneficiaries per CMHC. We then assumed that, in order to comply with the 40 percent requirement (§ 485.918(b)(1)(v)), those 60 beneficiaries only accounted for 60 percent of an average CMHC's total patient population. This means that an average CMHC also treated another 40 clients who did not have Medicare as a payer source, for a total of 100 clients (Medicare + non-Medicare) in an average CMHC. Therefore, all CMHCs combined would have approximately 2,080 non-PHP clients per year (40 per CMHC), and approximately 20,800 assessments would be reduced nationwide per year (2,080 patients × 10 assessments per patient). We estimate that documenting each assessment update requires 10 minutes of a CMHC clinician's time, for a total savings of 3,466 hours nationwide (1,666 hours × 20,800 assessment updates). At a cost of $7.33 for a mental health counselor to document each assessment, the total cost savings would be $152,464 ($7.33 × 20,800 assessments).

Y. ICRs Regarding Portable X-Ray Services (§§ 486.104(a) and 486.106(a))

We propose to revise the requirements for portable x-ray technologist personnel qualifications at § 486.104 to align the current requirements at § 486.104(a)(1), (2), (3), and (4) with those for hospital radiologic technologists at § 482.26(c)(2) which are focused on the qualifications of the individual performing services as permitted by State law. Although changing the qualifications would require management time, with the associated cost of those hours, in order to revise the internal personnel descriptions and qualifications, we believe that this proposed change would impose no burden because maintaining internal personnel descriptions and qualifications is a standard business practice. Therefore, this burden would not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

We propose to revise the requirements for portable x-ray orders at § 486.106(a)(2). We propose to remove the requirement that physician or non-physician practitioner's orders for portable x-ray services must be written and signed. We also propose to replace the specific requirements related to the content of each portable x-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable x-ray services. These proposed changes would simplify the ordering process for portable x-rays and promote the use of more efficient ordering methods, such as electronic orders.

This change would allow for portable x-ray services to be ordered in writing, by telephone, or by electronic methods. The change would also streamline the ordering process by avoiding the need to write two separate orders for the same study, one to meet the Medicare payment requirements in accordance with § 410.32 and its associated Manual guidance, and another to meet the content requirements of the regulation set forth at § 486.106. We believe the proposed change would allow for additional ordering flexibility to streamline ordering practices. In the information collection request (OMB control number 0938–0338) we estimate

that the current order requirements would impose the following burdens:

- 3 minutes to write an order × 3,986,000 portable x-rays exams ordered = 199,300 hours × $69/hour for a nurse = $13,751,700.
- $1 for printing and faxing verbal orders to physician offices for signature × 2,500,000 verbal orders = $2,500,000.
- 2,000,000 follow-up calls regarding the status of faxes × 10 minutes of time for clerical staff (5 minutes for portable x-ray clerical staff + 5 minutes for ordering physician clerical staff) = 333,333 hours × $32/hour = $10,666,656.

All of these burdens would be eliminated by revising the current ordering standards. Therefore, we estimate a proposed information collection savings of $26,918,356 from this proposed change.

Z. ICRs Regarding RHC and FQHC Provision of Services (§ 491.9(b)(4))

There are currently more than 4,100 RHCs and approximately 1,400 FQHC organizations furnishing services at approximately 12,000 or more total locations. Many FQHC organizations have multiple delivery sites, so to be as accurate as possible, our burden reduction calculations are based on the most recent data available, which shows that as of May 2017, there were 4,160 RHCs and 7,874 FQHC delivery sites. All CMS-certified sites are subject to our requirements and we are therefore utilizing the total number of current sites in our burden reduction calculations.

We propose to revise § 491.9(b)(4) to reduce the number of times that RHCs and FQHCs perform a review of all their policies and procedures. Changing from an annual review to a review every other year would reduce the burden on RHCs and FQHCs by half in a given period of time. In the currently approved information collection request (OMB control number 0938–0334), we estimate that it would take a RHC or FQHC approximately 4 hours for clinical staff to review and make changes to policies and procedures annually, for a total of 48,136 hours for all 12,034 RHC and FQHC locations. In a 2-year period, RHCs and FQHCs would use 96,272 total hours to comply with the requirements to annually review all of their policies and procedures. Under the proposed change to a review every other year, we estimate that in a 2-year period, it will take a total of 48,136 hours, for a savings of 48,136 hours per year. We estimate a savings of $592 per facility (see Table 6) for a combined total savings of $7.1 million for 12,034 RHCs or FQHCs ($592 × 12,034 RHCs and FQHCs). We will submit a revised information collection request to OMB for approval.

TABLE 6—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per RHC/FQHC (Includes 100% benefit package)	Burden hours per RHC/FQHC	Cost estimate per RHC/FQHC
Physician	$198	2	$396
Mid-Level Provider (PA or NP)	98	2	196
Total	296	4	592

AA. ICRs Regarding RHC and FQHC Program Evaluation (§ 491.11(a))

We propose to revise § 491.11(a) to reduce the number of times that RHCs and FQHCs carry out or arrange for an annual evaluation of the total program. Changing from an annual evaluation to an evaluation every other year would reduce the burden on RHCs and FQHCs by half in a given period of time. In the currently approved information collection request (OMB control number 0938–0334), we estimate that it would take a RHC or FQHC approximately 6 hours for administrative and clinical staff to perform an evaluation of its total program annually for a total of 72,204 hours for all 12,034 RHC and FQHC locations. In a 2-year period, RHCs and FQHCs would use 144,408 total hours to comply with the requirement for an evaluation of the total program. Under the proposed change to evaluate the total program every other year, we estimate a hourly savings of 72,204 total hours and a cost savings of $802 per facility (see Table 7), for a combined total savings of $9.7 million for 12,034 RHCs or FQHCs ($802 × 12,034 RHC and FQHC locations).

TABLE 7—HOURLY WAGES AND BURDEN HOURS

Position	Hourly wage per RHC/FQHC (Includes 100% benefit package)	Burden hours per RHC/FQHC	Cost estimate per RHC/FQHC
Administrator/Health Services Manager	$105	2	$210
Physician	198	2	396
Mid-Level Provider (PA or NP)	98	2	196.00
Total	401	6	802

BB. ICRs Regarding Emergency Preparedness for Providers and Suppliers

1. Review of the Emergency Preparedness Program

At § 482.15(a), (b), (c), and (d) for hospitals and parallel regulatory citations for other facilities, we propose to allow providers to review their program at least every 2 years. As of May 2017, there were approximately 74,246 total facilities. All are required to review their emergency preparedness program annually, which includes a review of their emergency plan, policies and procedures, communication plan, and training and testing program.

For our analysis, we estimate that reducing this requirement from annually to biennially would reduce compliance costs related to review of the emergency plan by 50 percent. The methodology used for our cost estimate analysis generally mirrors the methodology used for the annual review of the emergency plan Emergency Preparedness final rule (81 FR 63930) with a 50 percent reduction in the cost estimate calculation; however, after receiving additional feedback from stakeholders, we have determined that we underestimated the amount of time it would take to review the emergency plan. As a result, we have presented current burden hours associated with reviewing the emergency plan that reflects the increased associated burden hours relative to the information collection request for this provision (OMB control number 0938–1325). As in the Emergency Preparedness final rule (81 FR 63930), we assume that the individuals involved in the review of the emergency plan include an administrator, director of nursing, a RN, a physician, a social worker, a counselor, and an office manager, depending on the facility type. Based on May 2016 BLS salary data, we calculated the hourly mean wage for each position for this requirement identified in the Emergency Preparedness final rule (81 FR 63930).

We estimate that the proposed change will accrue a total annual cost savings of $94,312,719 and 187 burden hours saved. We list a detailed calculation for each facility below, based on facility numbers available as of May 2017:

- *RNHCIs:* Combined total savings of $9,540 for 18 RNHCIs ((8 burden hours for an administrator at $105 plus 5 burden hours for a director of nursing at $44 per hour) × 18 RNHCIs × 50 percent).
- *ASCs:* Combined total savings of $6,134,928 for 5,557 ASCs ((8 burden hours for an administrator at $108 per hour plus 4 burden hours for a physician at $198 per hour plus 8 burden hours for a quality improvement RN at $69 per hour) × 5,557 ASCs × 50 percent).
- *Hospices:* Combined total savings of $5,781,832 for 4,489 hospice facilities ((8 burden hours for an administrator at an hourly wage of $105 per hour plus 4 burden hours for a physician at $198 per hour plus 4 burden hours for a counselor at $44 per hour plus 4 burden hours for a social worker at $54 per hour plus 8 burden hours for a RN at $69 per hour) × 4,489 hospices × 50 percent).
- *PRTFs:* Combined total savings of $556,512 for 374 PRTFs ((8 burden hours for an administrator $105 per our plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a RN at $69 per hour) × 374 PRTFs × 50 percent).
- *PACE:* Combined total savings of $226,476 for 233 PACE organizations ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a home care coordinator at $69 per hour plus 8 burden hours for a RN at $69 per hour) × 233 PACE organizations × 50 percent).
- *Hospitals:* Combined total savings of $11,933,532 for 5,031 hospitals ((8 burden hours for an administrator at $108 per hour plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a risk management director at $105 per hour plus 8 burden hours for a quality assurance nurse at $69 per hour plus 8 burden hours for a facility director at $96 per hour plus 4 burden hours for a medical secretary at $34 per hour) × 5,031 hospitals × 50 percent).
- *LTCF:* Combined total savings of $25,562,016 for 15,663 LTCF facilities ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a director of nursing at $105 per hour) × 15,663 LTCFs × 50 percent).
- *ICF/IID:* Combined total savings $3,402,126 for 6,097 ICF/IIDs ((8 burden hours for an administrator at $105 per hour plus 4 burden hours for a RN $69 per hour) × 6,097 ICF/IIDs × 50 percent).
- *HHA:* Combined total savings of $16,259,712 for 12,624 HHAs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a nursing director at $105 per hour plus 8 burden hours for a director of rehab at $84 per hour plus 4 burden hours for an office manager at $56 per hour) × 12,624 HHAs × 50 percent).
- *CORF:* Combined total savings of $142,128 for 188 CORFs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a physical therapist at $84 per hour) × 188 CORFs × 50 percent).
- *CAH:* Combined total savings of $1,643,832 for 1,343 CAHs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a director of nursing at $105 per hour plus 8 burden hours for a facility director at $96 per hour) × 1,343 CAHs × 50 percent).
- *Organizations:* Combined total savings of $1,220,688 for 2,076 Organizations ((8 burden hours for an administrator at $105 per hour plus 4 burden hours for a physical therapist at $84 per hour) × 2,076 Organizations × 50 percent).
- *CMHCs:* Combined total savings of $146,832 for 161 CMHCs ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a RN at $69 per hour plus 8 burden hours for a social worker at $54 per hour) × 161 CMHCs × 50 percent).
- *OPOs:* Combined total savings of $119,016 for 58 OPOs ((8 burden hours for an OPO director at $105 per hour plus 8 burden hours for a physician at $198 per hour plus 8 burden hours for a QAPI director at $105 per hour plus 8 burden hours for an organ procurement coordinator at $105 per hour) × 58 OPOs × 50 percent).
- *RHC/FQHC:* Combined total savings of $9,916,016 ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour) × 4,160 RHCs × 50 percent) $3,427,840 + ((8 burden hours for an administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour × 7,874 FQHCs × 50 percent) $6,488,176).
- *ESRD Facilities:* Combined total savings of $11,064,392 for 6,898 dialysis facilities ((8 burden hours for an administrator at $105 per hour plus 8 burden hour for a medical director/physician at $198 per hour plus 8 burden hours for a nurse manager at $105) × 6,898 dialysis facilities × 50 percent) as shown in Table 8.

TABLE 8—COST SAVINGS FOR ANNUAL REVIEW OF EMERGENCY PREPAREDNESS PLAN

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
RNHCIs	$530	$9,540 for 18 RNHCIs.
ASCs	1,104	$6,134,928 for 5,557 ASCs.
Hospices	1,288	$5,781,832 for 4,489 hospice facilities both inpatient and freestanding/home based.
PRTFs	1,488	$556,512 for 374 PRTFs.
PACEs	972	$226,476 for 233 PACEs.
Hospitals	2,372	$11,933,532 for 5,031 hospitals.
LTCFs	1,632	$25,562,016 for 15,663 LTCFs.
ICFs/IIDs	558	$3,402,126 for 6,097 ICF/IIDs.
HHAs	1,288	$16,259,712 for 12,624 HHAs.
CORFs	756	$142,128 for 188 CORFs.
CAHs	1,224	$1,643,832 for 1,343 CAHs.
Organizations	588	$1,220,688 for 2,076 Organizations.
CMHCs	912	$146,832 for 161 CMHCs.
OPOs	2,052	$119,016 for 58 OPOs.
RHCs/FQHCs	824	$9,916,016 for RHCs and FQHCs ($3,427,840 for 4,160 RHCs and $6,488,176 for 7,874 FQHCs).
ESRD Facilities	1,6332	$11,257,536 for 6,898 dialysis facilities.

2. Contents of the Emergency Plan

At § 482.15(a)(4) for hospitals, and other parallel citations for the facilities mentioned in section II.J.2 of this proposed rule, we propose to eliminate the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and that facilities document participation in collaborative and cooperative planning efforts. We estimate that an administrator, or in the case of a hospital a community relations manager, a program director for a PACE, or a QAPI director for OPOs, would take 1 hour to document efforts to contact local, tribal, regional, State and Federal emergency preparedness officials and, when applicable, document the facility's participation in collaborative and cooperative planning efforts. We note that the Joint Commission (TJC)-accredited ASCs, TJC-accredited CAHs, and TJC-accredited hospitals have emergency preparedness requirements for developing an emergency preparedness plan that are comparable to the current emergency preparedness CoPs (81 FR 63937, 63954, and 63978 through 63979). Utilizing the same assumptions we used in the Emergency Preparedness final rule (81 FR 63937, 63954, and 63978 through 63979), we estimate that cost savings will accumulate from non-TJC accredited ASC, CAHs, and hospitals, since TJC-accredited ASCs, CAHs and hospitals are already required by the TJC to develop emergency preparedness plans. As a result, these facilities are excluded from the analysis given the requirements of their accreditation organization standards. Based on May 2016 BLS salary data, we calculate an hourly mean wage of $105 for an administrator, a PACE Program Director, or QAPI director and a cost savings of $105 per facility for RNHCIs, non-TJC accredited ASCs, hospices (both inpatient and freestanding), PRTFs, PACEs, LTCFs, ICF/IIDs, HHAs, CORFs, non-TJC accredited CAHs, Organizations, CMHCs, OPOs, RHC/FQHCs, and dialysis facilities ($105 hourly mean wage × 1 burden hour). For non-TJC accredited hospitals, we estimate an hourly mean wage of $114 for a community relations manager, and a $114 cost per facility ($114 × 1 hour). Therefore, we estimate the following for each facility affected by the proposed change, for a total savings of $7,179,117 and 18 burden hours. We list a summary of the calculation for savings accrued by removing this requirement for each facility in Table 9, based on facility numbers available as of May 2017.

TABLE 9—COST SAVINGS: DOCUMENTATION OF THE FACILITY'S PARTICIPATION IN COLLABORATIVE AND COOPERATIVE PLANNING EFFORTS

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
RNHCIs	$105	$1,890 for 18 RNHCIs.
ASCs (Non-TJC accredited)	105	$522,375 for 4,975 non-TJC accredited ASCs.
Hospices	105	$471,345 for 4,489 hospice facilities both inpatient and freestanding/home based.
PRTFs	105	$39,270 for 374 PRTFs.
PACEs	105	$24,465 for 233 PACEs.
Hospitals (Non-TJC accredited)	114	$157,662 for 1,383 non-TJC accredited hospitals.
LTCFs	105	$1,644,615 for 15,663 LTCFs.
ICFs/IIDs	105	$640,185 for 6,097 ICF/IIDs.
HHAs	105	$1,325,520 for 12,624 HHAs.
CORFs	105	$19,740 for 188 CORFs.
CAHs (Non-TJC accredited)	105	$103,215 for 983 non-TJC accredited CAHs.
Organizations	105	$217,980 for 2,076 Organizations.
CMHCs	105	$16,905 for 161 CMHCs.
OPOs	105	6,090 for 58 OPOs.
RHCs/FQHCs	105	$1,263,570 for RHCs and FQHCs ($436,800 for 4,160 RHCs and $826,770 for 7,874 FQHCs).

TABLE 9—COST SAVINGS: DOCUMENTATION OF THE FACILITY'S PARTICIPATION IN COLLABORATIVE AND COOPERATIVE PLANNING EFFORTS—Continued

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
ESRD Facilities	105	$724,290 for 6,898 dialysis facilities.

3. Training

At § 482.15(d)(1)(ii) for hospitals, and other parallel citations for other facilities mentioned in section II.J.2 of this proposed rule, we propose to require that facilities provide training biennially, or every 2 years, after facilities conduct initial training on their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated. We believe that the annual training requirement is too prescriptive as annual may not always be necessary. We propose to maintain the requirement that providers and suppliers develop a well-organized, effective training program that includes initial training for new and existing staff in emergency preparedness policies and procedures and would require training when the emergency plan is significantly updated. Facilities would have the flexibility to determine what is considered a significant update to the emergency plan.

For our analysis, we estimate that reducing this requirement from annually to biennially will reduce compliance costs related to providing emergency preparedness training by 50 percent. The methodology used for our cost estimate analysis mirrors the methodology used for the annual training requirement in the Emergency Preparedness final rule (81 FR 63930) with a 50 percent reduction in the cost estimate calculation. As in the Emergency Preparedness final rule (81 FR 63930), we assume that the individuals involved in the development and provision of training include an administrator, director of nursing, a RN, and an office manager, depending on the facility type. Providers and suppliers are expected to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Based on May 2016 BLS salary data, we calculated the hourly mean wage for each position for this requirement identified in the Emergency Preparedness final rule (81 FR 63930). We estimate that the proposed change will accrue a total annual cost savings of $33,267,864 and 111 burden hours. We list a detailed calculation for each facility below, based on facility numbers available as of May 2017 with a summary of these calculations provided in Table 10:

- *RNHCIs:* Combined total savings of $3,870 for 18 RNHCIs ((2 burden hours for an administrator at $105 plus 5 burden hours for a director of nursing at $44 per hour) × 18 RNHCIs × 50 percent).
- *ASCs:* Combined total savings of $1,258660 for 5,557 ASCs ((1 burden hour for an administrator at $108 per hour plus 5 burden hours for a quality improvement RN at $69 per hour) × 5,557 ASCs × 50 percent).
- *Hospices:* Combined total savings of $929,223 for 4,489 hospice facilities (6 burden hours for a RN at $69 per hour × 4,489 hospices × 50 percent).
- *PRTFs:* Combined total savings of $129,030 for 374 PRTFs (10 burden hours for a RN at $69 per hour × 374 PRTFs × 50 percent).
- *PACE:* Combined total savings of $96,462 for 233 PACE organizations (3 burden hours for a home care coordinator at $69 per hour plus 9 burden hours for a RN at $69 per hour × 233 PACE organizations × 50 percent).
- *Hospitals:* As we stated in the Emergency Preparedness final rule (81 FR 63958), TJC-accredited hospitals are required to train their staff for their assigned roles during emergencies (CAMH, Standard EC.4.16, Eps 1–2, p. EC–13e). In addition, the TJC-accredited hospitals also must provide on-going training to their staff, including training on specific job-related safety (CAMH, Standard HR–2.30, EP 4, CAMH Refreshed Core, January 2008, p. HR–11), and we expect that emergency preparedness is part of such on-going training. As a result, we estimate a combined total savings of $2,015,031 for 1,383 non-TJC accredited hospitals (2 burden hours for an administrator at $108 per hour plus 6 burden hours for a risk management director at $105 per hour plus 28 hours for a healthcare trainer (RN) at $69 per hour plus 4 burden hours for a medical secretary at $34 per hour × 1,383 hospitals × 50 percent).
- *LTCF:* Combined total savings of $8,223,075 for 15,663 LTCFs (2 burden hours for an administrator at $105 per hour plus 8 burden hours for a director of nursing at $105 per hour × 15,663 LTCFs × 50 percent).
- *ICF/IID:* Combined total savings $1,691,918 for 6,097 ICF/IIDs (2 burden hours for an administrator at $105 per hour plus 5 burden hours for a RN $69 per hour × 6,097 ICF/IIDs × 50 percent).
- *HHA:* Combined total savings of $7,902,624 for 12,624 HHAs (2 burden hours for an administrator at $105 per hour plus 2 burden hours for a nursing director at $105 per hour plus 2 burden hours for a director of rehab at $84 per hour plus 2 burden hours for an office manager at $56 per hour plus 8 burden hours for a director of training at $69 × 12,624 HHAs × 50 percent).
- *CORF:* Combined total savings of $73,038 for 188 CORFs (5 burden hours for an administrator at $105 per hour plus 3 burden hours for a physical therapist at $84 per hour × 188 CORFs × 50 percent).
- *CAH:* Combined total savings of $968,974 for 1,343 CAHs (2 burden hours for an administrator at $105 per hour plus 9 burden hours for a director of nursing at $105 per hour plus 3 burden hours for a facility director at $96 per hour × 1,343 CAHs × 50 percent).
- *Organizations:* Combined total savings of $828,324 for 2,076 Organizations (6 burden hours for an administrator at $105 per hour plus 2 burden hours for a physical therapist at $84 per hour × 2,076 Organizations × 50 percent).
- *CMHCs:* Combined total savings of $55,545 for 161 CMHCs (10 burden hours for a psychiatric RN at $69 per hour × 161 CMHCs × 50 percent).
- *OPOs:* Combined total savings of $111,012 for 58 OPOs (2 burden hours for a director at $114 per hour plus 2 burden hours for a medical director/ physician at $198 per hour plus 12 burden hours for a QAPI director at $105 per hour plus 8 hours for an organ procurement coordinator at $105 per hour plus 16 burden hours for an education coordinator at $69 per hour × 58 OPOs × 50 percent).
- *RHC/FQHC:* Combined total savings of $6,125,306 ((2 burden hours for an

administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour × 4,160 RHCs × 50 percent) $2,117,440 + (2 burden hours for an administrator at $105 per hour plus 8 burden hours for a nurse practitioner/physician assistant at $101 per hour × 7,874 FQHCs × 50 percent) $4,007,866).

• *ESRD Facilities:* Combined total savings of $2,855,772 for 6,898 dialysis facilities (3 burden hours for an administrator at $105 per hour plus 1 burden hour for a medical director/physician at $198 per hour plus 3 burden hours for a nurse manager at $105 × 6,898 dialysis facilities × 50 percent).

TABLE 10—COST SAVINGS: TRAINING

Provider/supplier	Cost savings per provider/supplier	Combined total savings
RNHCIs	$215	$3,870 for 18 RNHCIs.
ASCs	226	$1,258,660 for 5,557 ASCs.
Hospices	207	$929,223 for 4,489 hospice facilities both inpatient and freestanding/home based.
PRTFs	345	$129,030 for 374 PRTFs.
PACEs	414	$96,462 for 233 PACE organizations.
Hospitals (Non-TJC accredited)	1,457	$2,015,031 for 1,383 non-TJC accredited hospitals.
LTCFs	525	$8,223,075 for 15,663 LTCFs.
ICFs/IIDs	278	$1,691,918 for 6,097 ICF/IIDs.
HHAs	626	$ 7,902,624 for 12,624 HHAs.
CORFs	389	$73,038 for 188 CORFs.
Organizations	399	$828,324 for 2,076 Organizations.
CAHs	721	$968,974 for 1,343 CAHs.
CMHCs	345	$55,545 for 161 CMHCs.
OPOs	1,914	$1111,012 for 58 OPOs.
RHCs/FQHCs	509	$6,125,306 for RHCs and FQHCs ($2,117,440 for 4,160 RHCs and $4,007,866 for 7,874 FQHCs).
ESRD Facilities	414	$2,855,772 for 6,898 dialysis facilities.

4. Testing

Finally, at § 482.15(d)(2), we propose to require that providers of inpatient services mentioned in section II.J.2 of this proposed rule conduct two testing exercises annually, one of which may be an exercise of their choice that must be either a community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, a tabletop exercise or workshop that includes a group discussion led by a facilitator. We estimate that revising this requirement to include additional options for the types testing exercises that may be conducted for one of the two annually required exercises will provide greater flexibility for these providers. Given that these providers are currently required to conduct two testing exercises annually, and because they may choose to conduct the same types of testing exercises, we do not anticipate that this requirement will impose a burden upon providers of inpatient services and as such, this revision would not result in a savings of burden hours or dollars.

We propose to require that providers of outpatient services mentioned in section II.J.2 of this proposed rule conduct one testing exercise annually which must be either a community-based full-scale exercise (if available) or an individual facility-based functional exercise every other year, and in the opposite years, may be either a community-based full-scale exercise (if available), a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

For our analysis, we estimate that reducing this requirement from biannually to annually for outpatient providers will reduce compliance costs related to conducting emergency preparedness testing by 50 percent. The methodology used for our cost estimate analysis mirrors the methodology used for the biannual testing requirement in the Emergency Preparedness final rule (81 FR 63930) with a 50 percent reduction in the cost estimate calculation. As in the Emergency Preparedness final rule (81 FR 63930), we will assume that the same individuals involved with developing training would typically also develop the scenarios, materials, as well as any accompanying documentation associated with testing exercises. Based on May 2016 BLS salary data, we calculated the hourly mean wage for each position for this requirement identified in the Emergency Preparedness final rule (81 FR 63930) and decreased the cost by 50 percent due to the 50 percent reduction in the frequency requirement.

We estimate that the proposed change will accrue a total annual cost savings of $9,117,425 and 25 burden hours. We list a detailed calculation for each facility below, based on facility numbers available as of May 2017 with a summary of these calculations provided in Table 11:

• *ASCs:* Combined total savings of $1,066,944 for 5,557 ASCs ((1 burden hour for an administrator at $108 per hour plus 4 burden hours for a quality improvement RN at $69 per hour) × 5,557 ASCs × 50 percent).

• *Freestanding/home-based hospices:* Combined total savings of $557,520 for 4,040 hospice facilities (4 burden hours for a RN at $69 per hour × 4,040 hospices × 50 percent).

• *PACE:* Combined total savings of $40,193 for 233 PACE organizations (4 burden hours for a home care coordinator at $69 per hour plus 1 burden hours for a RN at $69 per hour × 233 PACE organizations × 50 percent).

• *HHA:* Combined total savings of $3,970,248 for 12,624 HHAs (1 burden hour for an administrator at $105 per hour plus 3 burden hours for a nursing director at $105 per hour plus 1 burden hours for a director of rehab at $84 per hour plus 1 burden hour for an office manager at $56 per hour plus 1 burden hours for a director of training at $69 × 12,624 HHAs × 50 percent).

• *CORF:* Combined total savings of $55,272 for 188 CORFs (4 burden hours for an administrator at $105 per hour plus 2 burden hours for a physical therapist at $84 per hour × 188 CORFs × 50 percent).

• *Organizations:* Combined total savings of $305,172 for 2,076 organizations (2 burden hours for an administrator at $105 per hour plus 1

burden hour for a physical therapist at $84 per hour × 2,076 organizations × 50 percent).

• *CMHCs:* Combined total savings of $22,218 for 161 CMHCs (4 burden hours for a psychiatric RN at $69 per hour × 161 CMHCs × 50 percent).

• *OPOs:* Combined total savings of $12,673 for 58 OPOs (3 burden hours for a QAPI director at $105 per hour plus 2 burden hours for an education coordinator at $69 per hour × 58 OPOs × 50 percent).

• *RHC/FQHC:* Combined total savings of $3,086,721 ((2 burden hours for an administrator at $105 per hour plus 3 burden hours for a nurse practitioner/physician assistant at $101 per hour × 4,160 RHCs × 50 percent) + (2 burden hours for an administrator at $105 per hour plus 3 burden hours for a nurse practitioner/physician assistant at $101 per hour × 7,874 FQHCs × 50 percent)).

• *ESRD:* As identified in the Emergency Preparedness final rule (81 FR 64006), the current CFCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (§ 494.60(d)(4)(ii)); thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency preparedness plans. As a result, ESRDs are not included in the burden calculation.

TABLE 11—COST SAVINGS: TESTING

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
ASCs	$192	$1,066,944 for 5,557 ASCs.
Hospices (freestanding/home-based)	138	$557,520 for 4,040 hospices.
PACEs	173	$40,193 for 233 PACE organizations.
HHAs	314	$3,970,248 for 12,624 HHAs.
CORFs	294	$55,272 for 188 CORFs.
Organizations	147	$305,172 for 2,076 Organizations.
CMHCs	138	$22,218 for 161 CMHCs.
OPOs	226	$13,137 for 58 OPOs.
RHCs/FQHCs	256	$3,086,721 ($1,067,040 for 4,160 RHCs and $2,019,681 for 7,874 FQHCs).

We will submit a revised information collection request to OMB to account for the burden hour and cost savings.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

All major and many ostensibly minor government regulations should undergo periodic review to ensure that they do not unduly burden regulated entities or the American people, and reflect current knowledge as to regulatory effects. In recent years, we have revised the CoPs and CfCs to reduce the regulatory burden on providers and suppliers. In doing so, we identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and States could use to improve or enhance patient health and safety. We also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for patients while reducing burden on providers of care, and we identified non-regulatory changes that would increase transparency and allow CMS to become a better business partner. In accordance with these goals, we published three final rules that identified unnecessary, obsolete, or excessively burdensome regulations on health care providers, suppliers, and beneficiaries. These rules further increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care:

• ''Reform of Hospital and Critical Access Hospital Conditions of Participation'', published May 16, 2012 (77 FR 29034);

• ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'', published May 16, 2012 (77 FR 29002) and;

• ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II'', published May 12, 2014 (79 FR 27105).

These reforms, however, did not exhaust the potential for burden-reducing reforms. We have continued to consult with regulated entities, have reviewed new research findings, have reviewed comments on previous rulemakings, and in these and other ways have identified additional reforms. These reforms are addressed in this proposed rule.

This proposed rule is not just a continuation of our efforts to reduce regulatory burden but also directly responds to the January 30, 2017 Executive Order ''Reducing Regulation and Controlling Regulatory Costs'' (Executive Order 13771). We propose changes to the current CoPs or CfCs that will simplify and streamline the current regulations and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing providers to focus on providing high-quality healthcare to their patients. This proposed rule will also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain requirements for providers and suppliers and remove obsolete, duplicative, or unnecessary requirements. Ultimately, these proposals balance patient safety and quality, while also providing broad regulatory relief for providers and suppliers, and reducing the associated burden on patients.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995

(March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget. This proposed rule would create ongoing cost savings to providers and suppliers in many areas. Other changes we have proposed would clarify existing policy and relieve some administrative burdens. We have identified other kinds of savings that providers and patients will realize throughout this preamble, and substantial lifesaving benefits. These life-saving effects arise by removing the incentives created by the current transplant center regulations to decline to transplant patients with slightly lower probability of success, and to decline to use organs with a slightly lower probability of success.

We welcome public comments on all of our burden assumptions and estimates as well as comments identifying additional reforms that should be considered for future rulemakings. As discussed later in this regulatory impact analysis, substantial uncertainty surrounds these estimates and we especially solicit comments on either our estimates of likely impacts or the specific regulatory changes that drive these estimates.

As stated in the ICR section of this proposed rule, we obtained all salary information from the May 2016 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at *https://www.bls.gov/oes/2016/may/oes_nat.htm* and calculated the added value of 100 percent for overhead and fringe benefits.

TABLE 12—SECTION–BY–SECTION ECONOMIC IMPACT ESTIMATES

Provider and supplier type and description of proposed provisions	Frequency	Number of affected entities	Estimated annual savings or benefits ($ millions)
Religious Nonmedical Health Care Institutions:			
• Discharge Planning	As patients are discharged (Estimated 619 annual discharges).	18	*
Ambulatory Surgical Centers:			
• Governing Body and Management	Upon failed hospital transfer agreement attempts.	5,557	*
• Patient Admission, Assessment and Discharge (History and Physical).	Every patient registration at an ASC or at a hospital outpatient/ambulatory surgery department.	5,557 (ASCs) 5,031 (Hospitals)	454
• Medical Records	Recurring annually	5,557	0
Hospices:			
• Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.	Recurring annually	1,151	80
• Hospices That Provide Hospice Care to residents of a SNF/NF or ICF/IID.	Recurring annually	4,602	*
• Hospice Aide and Homemaker Services	Recurring annually	3,498	2
Hospitals:			
• Quality Assessment and Performance Improvement Program.	Recurring annually	5,031	28
• Medical staff: Autopsies	Recurring annually	5,031	0
• Infection Control	Recurring annually	5,031	105
• Special requirements for hospital providers of long-term care services (''swing-beds'').	Recurring annually	1,724	30
• Special Requirements for Psychiatric Hospitals	Recurring annually	574	62
Transplant programs:			
• Various provisions related to performance**	Recurring annually	750	Not Quantified
Home Health Agencies:			
• Patient rights	Recurring annually	12,624	55
• Home health aide services	Recurring annually	12,624	0
• Clinical records	Recurring annually	12,624	0
Critical Access Hospitals:			
• Provision of Services	Recurring biennially	1,343	2
• Organizational structure	Recurring annually	1,343	*

TABLE 12—SECTION–BY–SECTION ECONOMIC IMPACT ESTIMATES—Continued

Provider and supplier type and description of proposed provisions	Frequency	Number of affected entities	Estimated annual savings or benefits ($ millions)
• Special requirements for CAH providers of long-term care services (''swing-beds'').	Recurring annually	1,246	86
Comprehensive Outpatient Rehabilitation Facilities:			
• Utilization Review Plan	Recurring annually	188	*
Community Mental Health Centers:			
• Assessment Update	Recurring annually	52	*
Portable X-Ray Services:			
• Qualifications of X-ray technicians***	Annual	500	31
• Removing written orders	Annual	500	29
RHC (4,160 clinics) & FQHC (7,874 center locations):			
• Provision of Services	Recurring biennially	12,034	7
• Program Evaluation	Recurring biennially	12,034	9
Emergency Preparedness for Providers and Suppliers:			
• Annual Review of Emergency Preparedness Program	Recurring annually	72,844	94
• Emergency Plan	Recurring annually	68,254	7
• Training and Testing-Training Program	Recurring annually	69,196	33
• Training and Testing-Testing	Recurring annually	36,971	9
Total Annual Savings			1,123
Life-extending benefits for transplant patients			Not Quantified

*Amount is less than one million dollars.
**These include proposed changes to the following requirements: Special Requirements for Transplant Programs; Data submission, Clinical Experience, and Outcome Requirement for Re-approval of Transplant Programs; and Special Procedures for Approval and Re-Approval of Organ Transplant Programs.
***This estimate is for first full year savings only and will increase in future years.

C. Anticipated Effects

1. Effects on Religious Nonmedical Health Care Institutions

As detailed in the Collection of Information section of this rule, we propose to reduce the discharge planning requirements for RNHCIs because RNHCIs do not provide medical treatment or services. Most patients are discharged to home or to another facility that also does not provide medical treatment or services. Although all patients must have a discharge planning evaluation, not all patients require a discharge plan. The discharge planning cost would be reduced by an estimated $27,013.16.

2. Effects on Ambulatory Surgical Centers and Hospital Outpatient/ Ambulatory Surgery Departments

As of May 2017 there were 5,557 Medicare-participating ASCs. We proposed to revise the ASC CfCs in order to reduce unnecessary duplications and streamline processes in order to reduce ASC compliance burden while maintaining minimum standards for patient safety and care. The specific savings for each proposed change are described later in this section of this proposed rule. At § 416.41(b)(3), we propose to remove the requirements related to transfer agreements and admitting privileges. This change would eliminate the administrative burden associated with preparing an agreement for signature and going through the hospital credentialing process in order to obtain admitting privileges. Currently, all Medicare-certified ASCs are meeting the transfer agreement or admitting privileges requirement with the exception of approximately twenty ASCs that have tenuous relationships with their local hospital. We estimate the ASCs that do have difficulty with meeting this requirement would appreciate the annual burden savings of 2 to 4 administrator hours spent on paperwork and documentation. For those already with the transfer agreements in place, there would not be any more follow-up burden related to renewals or updates to the documents. We estimate the savings at less than $10,000 overall and largely believe this change will not produce significant savings, however, it does affect twenty or more ASCs in the short term by removing the transfer agreement requirement. We welcome any feedback related to the time and effort for those ASCs that have secured an agreement, and if we have underestimated the savings of removing this transfer agreement in the future. As previously discussed, the enactment of EMTALA and its increasingly effective enforcement over time has rendered these transfer and admitting privileges obsolete and unnecessary. To put this point in perspective, emergencies or other unforeseen adverse events can arise in any ambulatory medical or dental setting, or in home settings. Over time, ''911'' emergency calls and direct ambulance responses have become standard operating procedures virtually nationwide, regardless of the place in which the problem arose. Under modern procedures, emergency responders (and patients themselves) take patients to hospital emergency rooms without regard to prior agreements between particular physicians and particular hospitals. Indeed, the most appropriate emergency treatment setting for a particular patient may not be one involving such an agreement even where the agreement exists. Of course, nothing prevents particular arrangements where a hospital and ASC agree that this is beneficial for a particular type of surgery or patient condition and where patient transport can be appropriately arranged to reflect this. Accordingly, we estimate that there will be no consequential adverse health effects of this proposed change, and therefore estimate no medical costs.

There will be competitive benefits in those places where an ASC will now be allowed to operate and provide care at reduced cost compared to inpatient treatment. Nonetheless, we believe that the number of affected areas and facilities are few, and that annual benefits are unlikely to reach the

million dollar range. We welcome comments on these effects and on the preceding analysis of health effects.

At § 416.52 we propose to replace the requirement that every patient must have a comprehensive H&P within 30 days prior to surgery in an ASC with a requirement that allows the operating physician and ASC to determine which patients would require more extensive testing and assessment prior to surgery. We believe that this change would reduce patient and provider burden in a multitude of ways that includes the community-based physician, the ASC, and the patient. We believe that in almost all situations ASCs can reasonably rely on existing H&P results that are more than 30 days old and then are updated by patient responses on the day of surgery, but we cannot forecast with any precision what medical specialty societies, ASC governing bodies, hospital governing bodies, or accreditation bodies will decide to do in replacing the current requirement. Therefore, we do not forecast specific cost savings at this time, and solicit public comments to help us with our estimate in the final rule.

For ASCs, we believe this change would reduce administrative burden by decreasing the amount of time that ASC personnel spend following up on patient visits to obtain the necessary H&P information and that it will provide for an increase in scheduling flexibility for the facility. We believe these changes may have the effect of improving patient satisfaction and increasing positive patient referrals for the ASC.

For community-based healthcare providers, to include primary care providers, we believe this change would reduce unnecessary examinations that are required to be performed and reduce administrative paperwork burden associated with providing ASCs with the necessary H&P documentation and additional testing requirements. This change may potentially provide an opportunity for increased access to community-based providers because of available appointments that are not being filled by unnecessary patient appointments for H&P requirements for surgery in an ASC. Those vacant appointments may also generate more revenue.

For patients, we believe this change would reduce the time spent to prepare for surgery (time in community-based physician office, travel time and costs, time missed from the work place and lost productivity) and the cost associated with co-pays and other healthcare cost sharing requirements.

Finally, we believe this change would reduce expenses for healthcare insurers to include Medicare, Medicaid, and private healthcare insurance companies. This change would reduce costs associated with reduced pre-operative exams, laboratory testing, chest radiographs, and echocardiograms.

It is difficult to estimate the savings from this change, because they depend on a number of factors previously described, and additional factors for which we do not have precise measures, such as the number of patients (both Medicare and non-Medicare) who received two or more ASC services within the 30-day window allowed for one physical examination. This is a common occurrence because, for example, patients often receive cataract surgery on one eye and then, a week later, on the other eye. Furthermore, there are an immense number of different outpatient surgical services. At present, for example, there are about 137 services that account for about 90 percent of ASC volume, and these services are highly diverse, as shown in Table 13.

TABLE 13—TWENTY MOST FREQUENT ASC SERVICES IN 2015

Surgical service	Rank	Percent of volume
Cataract surgery w/IOL insert	1	18.60
Upper GI endoscopy, biopsy	2	8.2
Colonoscopy and biopsy	3	6.8
Lesion removal colonoscopy (snare technique)	4	5.6
Inject foramen epidural: Lumbar, sacral	7	4.8
After cataract laser surgery	6	4.4
Injection spine: Lumbar, sacral (caudal)	8	3.3
Inject paravertebral: Lumbar, sacral	9	3.1
Diagnostic colonoscopy	5	2.3
Colorectal screen, high-risk individual	10	2.0
Colorectal screen, not high-risk individual	12	1.9
Cataract surgery, complex	11	1.6
Injection procedure for sacroiliac joint, anesthetic	19	1.3
Cystoscopy	15	1.2
Upper GI endoscopy, diagnosis	13	1.0
Inject spine, cervical or thoracic	17	1.0
Revision of upper eyelid	16	0.9
Lesion removal colonoscopy (hot biopsy forceps)	14	0.8
Upper GI endoscopy, insertion of guide wire	18	0.8
Carpal tunnel surgery	20	0.7
Total	.....	70.4

Source: MEDPAC. Ambulatory surgical center services. 2017, p. 140.

In total, ASCs provided about 6.4 million services in 2015 (MEDPAC. Ambulatory surgical centers services, 2017, p. 139). If we assume that 25 percent of these had two or more services within the 30-day ''window'' allowed in the current rule, then another H&P with its associated battery of tests were required for each of the remaining 4.8 million individuals. Assuming that 5 percent of these would otherwise have already had an overall H&P and associated tests within 30 days of the surgery, 4.56 million persons would then require a new H&P and tests before surgery under the current requirements. In the great majority of cases involving eye or eyelid surgery of one kind or another, the ophthalmology examination preceding the ASC surgery would not have involved a

comprehensive H&P or battery of tests, and a similar situation would be involved for most other surgeries preceded by specialist rather than primary care visits.

Although we are unable to estimate the likely number of cases, one way to estimate the costs of these examinations and tests would be as follows. First, the H&P itself would cost approximately $100 (the exact amount depending on diagnostic details, and not necessarily corresponding to any particular payment schedule). The battery of tests would cost approximately $100, assuming both urine and blood testing, and, in some cases, an electrocardiogram, but only half of physical examinations (for example, few or no ophthalmologist exams) would include such tests. The travel of the patient to and from the physician office to obtain the examination and tests would on average require 1 hour, which when valued at the average wage rate in the economy of $24 (increased by 50 percent to include fringe benefits but not overhead) would cost about $36. In addition, ASCs incur substantial costs for the time and trouble needed to contact physician offices and arrange for the results to be delivered. The physician offices themselves would be put through the trouble of transferring those medical records. Assuming average time spent (the median would be less but a small number of difficult cases would bring the average well above the median) would reach 10 minutes, and the use of a general office clerk at $32 an hour, the cost per patient would average $5 per patient. A further cost arises because in many cases the examination and test results simply cannot be obtained timely, and a scheduled surgery has to be postponed. Assuming that in such cases a half hour of surgeon time (at $243 an hour) and a half hour of registered nurse (RN) time (at $69 an hour) is wasted, and that clerical time ($32 an hour) to reschedule averages 10 minutes, the average cost per postponement would be $161. (In some of these cases patient time would be wasted, as well as the time of family members accompanying the patient—we have not estimated these costs.)

Aggregating these calculations, one estimate of the annual costs of the current regulatory requirement, as shown in Table 14, could be as much as $972 million for ASCs and a similar amount for hospital outpatient surgery. For many and perhaps most cases, however, either the surgeon or the facility would decide that H&P information is needed for particular patients or particular procedures whether or not this regulatory requirement existed. Of course, it is unlikely that in such cases a strict 30-day window would be insisted on. Assuming that such examination and testing information would continue to be needed for 10 percent of all patients, and that in half of these cases the information would require a new examination and tests within a 30-day window, the net costs of the current regulatory requirement would be 5 percent less than the preceding calculations. Supposing that such examination and testing information would still be required for 50 percent of all patients, the costs of the current requirement and hence the potential savings from its reform would fall much further. Absent more specific information, the estimates of potential costs and savings in Table 14 are suggestive but not robust until or unless improved through public comment and additional information. In our summary estimates, we have assumed a range of savings from zero to 50 percent, with a midpoint of 25 percent.

As support for the 50 percent upper bound, we note that Chen CL, Lin GA, Bardach NS, Clay TH, Boscardin WJ, Gelb AW, Maze M, Gropper MA and Dudley RA, Preoperative Medical Testing in Medicare Patients Undergoing Cataract Surgery, New England Journal of Medicine 372:1530–1538, April 16, 2015, find that approximately 53 percent of Medicare cataract patients undergo pre-operative testing, none of which is mandated by CMS regulation. If these patients' physicians are cautious enough to currently pursue more preoperative activity (testing, H&P, etc.) than what is required, or state or hospital rules are driving physician behavior beyond what Medicare necessitates, then there is little reason to believe that that behavior will change with the finalization of this rule. Given that other procedures tend to be more invasive than cataract surgery, pre-operative caution on the part of physicians is likely to be even greater in the non-cataract context. Indeed, Benarroch-Gampel J, Sheffield KM, Duncan CB, Brown KM, Han Y, Townsend CM and Riall TS, Preoperative Laboratory Testing in Patients Undergoing Elective, Low-Risk Ambulatory Surgery, Annals of Surgery 256(3):518–528, September 2012, and Fischer JP, Shang EK, Nelson JA, Wu LC, Serletti JM and Kovach SJ, Patterns of Preoperative Laboratory Testing in Patients Undergoing Plastic Surgery Procedures, Aesthetic Surgery Journal 1(1):133–141, January 2014, find that almost two-thirds of hernia procedures are preceded by testing, as are 62 percent of ambulatory plastic surgeries. This leaves an upper bound of 33 to 38 percent of non-cataract outpatient surgery H&P costs that could reasonably be expected to be avoided as a result of this rulemaking. In order to more successfully tailor the upper bound of potential cost savings to H&P activity—rather than just extrapolating from testing behavior—we request comment on the possibility of building on Chen et al.'s data and methodology to estimate the increased frequency of within-30-day office visits (presumed to be H&P) when ophthalmologist visits are at least 31 days prior to surgery relative to when ophthalmologist visits are no more than 30 days prior.

As noted in the medical literature previously discussed, Chung F, Yuan H, Yin L, Vairavanathan S, and Wong DT. Elimination of preoperative testing in ambulatory surgery. Anesth Analg. 2009 Feb, 108(s):467–75, there are no known consequential medical benefits from the testing often performed in association with the current regulatory requirements. This study covered hernia patients but similar results have been found in studies of cataract surgery. Accordingly, eliminating the testing could in theory produce very substantial annual ASC cost savings with no offsetting medical cost increases or harm to patients. H&P itself, however, is distinct from testing, and literature indicating that testing is wasteful does not necessarily speak to the importance of H&P. Therefore, if H&P is avoided, rather than more thoroughly integrated into same-day presurgical assessments, there could be adverse consequences to patients; these impacts have not been quantified.

As discussed in ''Provisions of the Proposed Regulations,'' section II.D. 2. of this proposed rule, there is a similar regulatory requirement for hospital outpatient surgery. Based on the substantial similarity between these two service settings, we also propose to eliminate these requirements for such surgery. Although we do not have detailed data for hospital outpatient surgery, it is widely agree to be roughly equal in size and composition to ASC surgery, though spending is higher because a higher payment schedule is used by some insurers, including Medicare, for most hospital outpatient surgery. Regardless, estimates should be based on economic costs, not any particular payment schedules. Accordingly, potential total annual savings, and hence benefits, for both settings taken together could be as much as $1.7 billion. This would depend on whether hospital-based outpatient

surgery decisions parallel those of independent ASCs.

If, after ASCs and hospitals make policy decisions on which types of outpatient/ambulatory surgery patients would require a comprehensive H&P, it is found that only 50 percent of current costs were continued, potential total annual savings, and hence benefits, for both settings taken together could be as much as $908 million, assuming that hospital-based outpatient surgery H&P policy decisions parallel those of independent ASCs. Alternatively, if 75 percent of current costs were continued, potential savings would be only about $454 million annually. While the literature shows that we can be reasonably certain that for some procedures, such as cataract surgery, few or possibly even no costs would be self-imposed, there may be other procedures where ensuing policy decisions would retain all current history and physical requirements, though likely removing the strict 30-day rule. Because of the proposed requirements, and other uncertainties, the potential savings from lifting the current requirements encompass at least this broad range and quite possibly more. Because there is great uncertainty in these estimates we have decided not to present a predetermined figure in this proposed rule. Instead, we are requesting public comments on all the parameters of our estimates to inform the estimates we will make in the final rule. We welcome information on likely decisions in both ASC and hospital outpatient settings, and if possible for the most common procedures shown in Table 13 and for the likelihood and cost saving effects for procedure and patient categories where the facility chooses to retain an external H&P requirement, but extends the time window to a year or some other period that is far longer than 30 days.

TABLE 14—CURRENT COSTS AND POTENTIAL ANNUAL SAVINGS FROM CREATING AND OBTAINING EXAMINATION AND TEST RESULTS

Type of cost	Unit cost	Number (M)	Current total cost ($M)	Twenty-five percent retained ($M)	Fifty percent retained ($M)	Seventy-five percent retained ($M)
Physical Examinations	$100	4.56	$456	$114	$228	$342
Test Batteries	100	2.28	228	57	114	171
Patient Travel Cost	36	4.56	164	41	82	123
Administrative Cost to ASC	5	4.56	23	6	11	17
Surgery Cancellations *	161	0.228	37	9	18	28
Total Cost, ASCs	.....	.....	908	227	454	681
Total Cost, Hospital Outpatient **	.....	.....	908	227	454	681
Total Cost	.....	.....	1,815	454	908	1,362
Total Savings	.....	.....	.....	1,362	908	454

* Based on information from a major ambulatory surgery facility, this estimate assumes that 5 percent of scheduled cataract operations are cancelled at the last minute since the required H&P information has not arrived from the physician office where the examination was performed and the tests ordered or performed. Staff salaries must still be paid. Our estimates assume one half hour of surgeon time wasted (at $243 an hour), one half hour of RN time wasted (at $69 an hour), and ten minutes of clerical time (at $32 an hour) to reschedule.

** Hospital outpatient savings assumed to be equal to ASC savings.

We assume that the one-time costs of developing such policies for hospital outpatient surgery in 5,031 Medicare-participating hospitals would be the same in the aggregate, though the mix of personnel used would be somewhat different and the cost at free-standing hospitals would likely be several times higher (for example, for involvement of the governing body and legal review). About 3,200 of these hospitals are in multi-hospital systems that would, however, reap economies of scale, and about 574 are psychiatric hospitals that we assume rarely perform surgery. In total, we estimate that, first year savings for both types of facilities would be $38 million less, regardless of the replacement rules that each facility imposed on itself.

There are possible alternatives, including limiting the regulatory reform to the lowest risk procedures, which would probably mean almost all procedures, excluding certain procedures from the regulatory reform, exempting ASCs, but not hospital outpatient departments, changing the 30-day requirement to something much longer in duration such as 6 months or a year, and likely others. Absent contrary evidence, however, we believe that relying on physician and facility judgment maximizes benefits and presents no consequential costs.

We welcome comments on these estimates and on both the proposal and any alternatives, and particularly welcome any evidence-based information that would inform both our ability to provide cost savings estimates and a policy choice between either the proposed reform or an alternative.

3. Effects on Hospices

As of May 2017 there are 4,602 Medicare participating hospices. We proposed to revise the hospice CoPs in order to reduce unnecessary duplications and streamline processes in order to reduce hospice compliance burden while maintaining minimum standards for patient safety and care.

At § 418.76(a) we propose to defer to State training and competency requirements, where they exist, for hospice aides. Deferring to state requirements would streamline the hiring process because hospices would not have to verify that a job candidate's qualifications meet or exceed the Federal standard in addition to verifying that the candidate meets State requirements.

According to the BLS, 408,920 aides are currently employed in ''home care''. The term ''home care'' encompasses both home health agency and hospice employers. There are 12,624 HHAs and 4,602 hospices, meaning that hospices represent 27 percent of the ''home care'' employer market. Thus, we conclude that hospices employ 110,408 aides (27 percent of all aide positions in ''home care''). Based on an informal survey conducted by the largest hospice industry association, 76 percent of

States have their own training and competency requirements, accounting for approximately 83,910 aide positions. Hospices in these states would benefit from the proposed change because they would be permitted to rely on the completion of state mandated training and competency programs to assure that a candidate is qualified for employment, and would no longer have to take the additional step of verifying that each potential job candidate also meet the Federal requirements. We assume a 25 percent turnover rate based on discussions with industry experts, or 20,978 aide job listings per year. Based on an assumed 20 candidates that would require the qualifications verification per job listing, we estimate that hospices must verify the training and competency program content and format for 419,560 candidates per year. We assume that it would take 10 minutes per candidate to verify compliance with the Federal requirements, for a total of 69,927 hours per year nationwide. At a cost of $32 per hour for a general office clerk to perform this check, we estimate that hospices will save $2,237,664 annually.

At § 418.106(a) we propose to delete the requirement that a hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. Not requiring the specific pharmacy advisement function would allow for more streamlined interdisciplinary group meetings. We assume that 25 percent of hospices currently use their own staff (employee or contract) for this function, and that this staff member is typically the nurse member of the interdisciplinary group. The nurse member of the interdisciplinary group is also required by § 418.56(a); therefore we believe that removing this requirement will not result in removing the expertise from the group. Rather, we believe that removing this requirement will remove the formulaic approach to interdisciplinary discussions whereby the group allots time in each meeting specifically for this discussion in order to assure regulatory compliance. In the absence of regulation, the interdisciplinary group would have the authority to decide whether the discussion is pertinent for a given patient and the information can be woven into the discussion at large. This approach has the potential to reduce the overall group discussion time, particularly for the 3 members of the interdisciplinary group that are not charged with being the pharmacology expert. Based on 1.6 million hospice patients and an assumed 3 interdisciplinary group meetings per patient, there are a total of 4,800,000 interdisciplinary group meetings per year. We assume that each interdisciplinary group meeting includes 2 minutes of time specifically related to discussing the results of the pharmacy advisement service for purposes of complying with the regulation, or 160,000 hours per year nationwide. At a cost of $299 per hour ($198 physician + $53 social worker + $48 pastoral counselor), we estimate that removing this requirement would save $47,840,000 annually.

Additionally, we believe that this change would reduce the specialist nursing time spent specifically on advisement services. We believe that moving away from a regulatory compliance ''check box'' approach would allow the specialist nurse to incorporate medication management more seamlessly into regular clinical practice. The 2008 Hospice CoP final rule (73 FR 32088) estimated a 1 hour burden per patient for expert pharmacy services (30 minute initial advisement per patient + 2 15 minute update advisements) for a total cost of $69 per patient for all advisement services (updated to 2017 dollars). We estimate that this proposed change would reduce that time by 50 percent, to 30 minutes per patient, resulting in a $35 per patient savings. Based on the assumption that 25 percent of hospices use their own employee to perform this function, we estimate that this reduction would occur for 400,000 patients nationwide (25 percent of 1.6 million hospice patients), for a total annual savings of $14,000,000.

Together with the previously stated estimate, total savings would be $47,840,000 + $14 million = $61,840,000 annually.

We propose to revise the requirement at § 418.106(d) to allow hospices to provide information regarding safe medication use, storage, and disposal in a more understandable manner. Under the current requirements, hospices are required to provide patients and families with a copy of the hospice's policies and procedures, which are not written in layperson terms. The proposed change would alleviate the burden associated with addressing the confusion created by the policies and procedures document. Following the initial cost of $483,210 (described in section III.E. of this rule) for developing new, more easily understandable materials for patient education, we believe that hospices would realize a savings of 10 minutes per patient because it would require less hospice staff time to explain the more understandable material. Based on an assumed 10 minutes of saved nursing time per patient, and 1.6 million patients, hospices would save 266,667 hours. At a cost of $69 per hour, the total savings would be $18,400,023.

First year: $18,400,023 savings − $483,210 initial year cost = $17,916,813 net savings.

Annually thereafter: $18,400,023 savings.

At § 418.112(f) we propose to allow hospices and long term care facilities the additional flexibility to negotiate the format and schedule for orienting long term care facility staff regarding certain hospice-specific information. We believe that this would allow for innovation and streamlining, and reduce hospice compliance costs related to this requirement by 20 percent. For purposes of our analysis only, we assume that a typical hospice conducts 6 orientation sessions per year, and that each orientation requires 2 hours of time from a hospice nurse. At a cost of $69 per hour, a typical hospice would spend $828 each year to orient long term care facility staff. Assuming a 20 percent reduction in burden that can be achieved through innovation and streamlining, a typical hospice would save $166 a year, or $763,932 savings annually for all 4,602 hospices.

Taken together, these proposed reforms would generate annual savings of approximately $82.8 million ($47.8 million for reduced interdisciplinary group meeting time + $14 million for reduced specialty nursing time + $18 million for streamlined controlled drug education practices + $2.2 million for streamlined hospice aide qualification requirements + $0.8 million for streamlined facility staff orientation). We welcome public comment regarding these burden estimates, and additional regulatory reforms to reduce the burden of the hospice CoPs.

4. Effects on Hospitals

As of May 2017, there were 5,031 Medicare participating hospitals. We propose to revise the hospital CoPs in order to simplify some requirements and streamline processes in order to reduce burden associated with hospital compliance with the Medicare CoPs while maintaining minimum health and safety standards. The specific savings for each proposed change are described below.

At § 482.21, we propose to allow for multi-hospital systems using a system governing body, as allowed under the CoPs, and that is legally responsible for two or more separately certified member hospitals, to have a unified QAPI program for the member hospitals subject to the system governing body. This will afford hospitals flexibility and the ability to gain efficiencies and achieve significant progress in quality by sharing best practices among all hospitals subject to the system governing body. This would be similar to current allowances for system governing bodies and unified medical staffs.

While there are no current requirements that explicitly prohibit the sharing of best practices across a system, the current requirements for each hospital to have its own separate and distinct QAPI program and Infection Control program certainly have inhibited and stifled sharing of best practices and innovations among individual hospitals within a system as we point out in the preamble to this proposed rule, and which we support with our reference to the Health Research and Educational Trust, in partnership with the American Hospital Association March 2010 publication entitled, ''A Guide to Achieving High Performance in Multi-Hospital Health Systems.'' This publication, along with positive public comments regarding unified medical staffs that we discussed in the May 2014 final rule and to which we refer in this proposed rule, clearly point to multi-hospitals more efficiently and effectively collecting, disseminating, and sharing innovations, solutions, and best practices for patient care to each of its member hospitals through these unified patient care programs.

Approximately 3,200 of the 5,031 Medicare-participating hospitals participate in a hospital system (American Hospital Association (AHA), *Fast Facts 2017* (*https://www.aha.org/system/files/2018-01/fast-facts-us-hospitals-2017_0.pdf*)). According to the 2017 AHA Guide, there are 424 multi-hospital systems. The current regulatory burden for compliance with the QAPI program requirement is approximately $10,000 annually per hospital or $50.3 million annually for all 5,031 hospitals. If we were to allow a unified QAPI program for multi-hospital systems, this would remove 3,200 hospitals from the total 5,031 (replaced by the 424 multi-hospital systems) for a total of 2,255 hospitals/multi-hospital systems that would still need to comply. The new regulatory burden would be a total of approximately $22.6 million annually (2,255 × $10,000), for an annual total savings of approximately $28 million. We welcome comments on the quantitative and non-quantitative portions of the preceding discussion and seek any empirical evidence that would improve the accuracy and thoroughness of the relevant benefits estimation.

We propose to remove the requirement for hospitals at § 482.22(d), which states that a hospital's medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. Because this requirement is redundant and more detailed, specific requirements regarding medical-legal investigative autopsies are required by individual state law, we do not anticipate that hospitals would accrue additional savings from this change. The benefit to hospitals from eliminating this requirement is realized through a reduction in burden from no longer having to comply with two similar requirements of the Federal government and the State government. Hospitals would instead be required to follow the more detailed, specific regulations of the state in which they are located.

At § 482.42, we propose to allow for multi-hospital systems using a system governing body as currently allowed under the CoPs, and that is legally responsible for two or more separately certified member hospitals, to have a unified infection control program for those member hospitals subject to the system governing body. This would allow hospitals flexibility and the ability to gain efficiencies and achieve significant progress in infection prevention and control. This would also be similar to current allowances for system governing bodies and unified medical staffs.

The current regulatory burden for compliance with the Infection Control program requirement is approximately $191 million annually for all hospitals or $38,000 per hospital. If we were to allow a unified Infection Control program for multi-hospital systems, this would remove 3,200 hospitals from the total 5,031 (replaced by the 424 multi-hospital systems) for a total of 2,255 hospitals/multi-hospital systems that would still need to comply. The new regulatory burden would be a total of approximately $86 million annually (2,255 × $38,000), for an annual total savings of approximately $105 million. We welcome comments on the quantitative and non-quantitative portions of the preceding discussion and seek any empirical evidence that would improve the accuracy and thoroughness of the relevant benefits estimation. At §§ 482.58(b)(1) and 485.645(d)(1) (cross-referenced long-term care requirement at § 483.10(f)(9)) we propose to remove the requirement for hospital and CAH swing-bed providers to provide the right for patients to choose to or refuse to perform services for the facility and if they so choose, (a) document in the resident's plan of care, (b) noting whether the services are voluntary or paid and (c) provide wages for the work being performed given the location quality, and quantity of work requiring comparable skills. We discuss the economic impact for this provision in the ICR section of this rule, which is estimated to be $32 million.

At § 482.58(b)(4) (and § 485.645(d)(4)) (cross-referenced long-term care requirement at § 483.24(c)), we propose to remove the requirement for hospital and CAH swing-bed providers to provide an ongoing activity program that is directed by a qualified therapeutic recreation specialist or an activities professional who meets certain requirements as listed at § 483.24(c)(2). We discuss the economic impact for this provision in the ICR section of this rule, which is estimated to be $81 million.

We propose to remove the requirement at §§ 482.58(b)(5) and 485.645(d)(5) (cross-referenced long-term care requirement at § 483.70(p)) for hospital and CAH swing-bed providers to employ a qualified social worker on a full-time basis if the facility has more than 120 beds. Given that this provision is not applicable to either provider type due to the regulatory requirements for each, it does not impose a burden upon hospitals and as such, its removal would not result in a savings of burden hours or dollars.

At §§ 482.58(b)(8) and 485.645(d)(8) (cross-referenced long-term care requirement at § 483.55(a)(1)) we propose to remove the requirement for hospital and CAH swing-bed providers to assist in obtaining routine and 24-hour emergency dental care to its residents. We discuss the economic impact for this provision in the ICR section of this rule, which is estimated to be $2.9 million for all hospital and CAH swing-bed providers.

At § 482.61(d), we propose to allow non-physician practitioners to document progress notes in accordance with State laws and scope of practice requirements. We discuss the economic impact for this provision in the ICR section, which is estimated at $54.7 million in savings for psychiatric hospitals.

5. Effects on Transplant Programs and Patients

There are approximately 750 Medicare approved transplant programs in the United States, of which 250 are kidney transplant programs. All Medicare approved transplant programs must be a part of a Medicare approved hospital, and many hospitals have several types of organ programs. Oversight of these programs occurs in two major ways: By the Organ Procurement and Transplantation Network (OPTN), which is a non-profit membership-based organization operated under a Federal contract administered by the Health Resources and Services Administration (HRSA), and by CMS under the CoPs. The current and long-term OPTN contractor is the United Network for Organ Sharing (UNOS), which performs many transplantation functions, including matching donated organs to waiting lists of patients who have failing organs, and reviewing the performance of transplant centers on a variety of criteria, including patient and organ survival. There is a third mechanism encouraging better transplant program performance, the SRTR (accessed at *https://www.srtr.org*). The SRTR, also operated under a HRSA contract, provides detailed data on the performance of all transplant programs, and allows the OPTN, individual transplant programs, and patients themselves to compare results on such vital metrics as patient survival rates after transplant.

For patients with most types of organ failure, a transplant is the only option for long-term survival. In the case of kidney failure, however, kidney dialysis is a viable medium-term and sometimes long-term option for most patients. On average these patients can survive a dozen or more years on dialysis; however, without a transplant, they suffer increasingly high morbidity and mortality rates. We provide Medicare coverage for such patients through the ESRD program. Under the ESRD program, patients receive dialysis treatment, usually three times a week, through machines that cleanse their blood in much the same way as healthy kidneys would do. Since its inception in 1973, more than one million patients have received treatment under this program. Kidney failure patients are unique in another way: Unlike most other organs, with the partial exception of some liver donations, it is possible for living individuals to donate ''live'' kidneys, whether the living donor is a relative or an unrelated altruistic donor. In the case of ESRD patients, the Medicare ESRD program serves almost all kidney failure patients, regardless of age, and these patients receive costly dialysis for a prolonged period of time. As is the case for all CoPs, our regulations for Medicare-approved organ transplant programs have the potential to protect all patients, not just Medicare beneficiaries.

As discussed earlier in this preamble, we have long regulated transplant programs, but put in place additional CoPs in the March 2007 final rule (72 FR 15198) in an effort to increase the quality of care by specifying minimal health and safety standards. In addition, outcome metrics (1 year graft and patient survival) were included in the regulation and mirrored the OPTN outcomes metrics as calculated by the SRTR. Over time, increased emphasis on organ and patient survival rates, as key metrics of transplant performance, created incentives for transplant programs to select organs most likely to survive after transplant without rejection, and to select recipients most likely to survive after the transplant. In particular, due to the increasing patient and organ survival rates over time, the 2007 standards have become increasingly stringent over time as an artifact of the performance calculation method established in the 2007 rule, an outcome that was never intended by CMS. In addition, the 2007 rule created performance standards that focused only on organ and patient survival rates for those who received a transplant, not on survival rates of patients awaiting transplant. We refer readers to a discussion of this problem in the following CMS compliance Guidelines that could only partially lighten this unintended regulatory burden at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-24.pdf.*

There is extensive literature on these incentives and other phenomena in transplant medicine that strongly suggests some unintended consequences on organ utilization (decreased use of ''marginal'' organs in their patients) and de-selection of some patients who are slightly less likely to survive for an extended period post-transplant. These unintended consequences have been anecdotal and measuring the extent to which they have occurred is difficult. In addition to the studies previously cited in the preamble (Adler et al., Schold et al., Dolgin et al., Stewart et al., Husain et al.), other studies on this issue include Kasiske B, Salkowski N, Wey A, Israni A, and Snyder J, ''Potential Implications of Recent and Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States,'' *American Journal of Transplantation,* Volume 16, Issue 12, December 2016, pages 3371–3377; Howard R, Cornell D, and Schold J, ''CMS Oversight, OPOs and transplant centers and the law of unintended consequences, *Clinical Transplantation,* Volume 23, Issue 6, November/December 2009, pages 778–783; and Abecassis M, Burke R, Klintmaim G, Matas A, Merion R, Millman D, Olhoff K, and Roberts J, ''American Society of Transplant Surgeons Transplant Center Outcome Requirements—A Threat to Innovation,'' *American Journal of Transplantation,* Volume 9, Issue 6, June 2009, pages 1279–1286; and Schold J, Miller C, Mitchell H, Buccine L, Flechner S, Goldfarb D, Poggio E, and Andreoni K, ''Evaluation of Flagging Criteria of United States Kidney Transplant Performance: How to Best Define Outliers,'' *Transplantation,* June 2017, Volume 101, Issue 6, pages 1373–1380. These studies regarding the reduced number of transplants that would otherwise have occurred, yielded several relevant facts. The number of deceased donor organs that are discarded has been increasing over time and for kidneys, is above 20 percent. For example, about 33 percent of kidneys recovered from donors age 50 to 64 are discarded, as are about 62 percent of kidneys recovered from donors age 65 or older (Hart A. et al., OPTN/SRTR 2015 ''Annual Data Report: Kidney.'' Accessed at *http://onlinelibrary.wiley.com/doi/10.1111/ajt.14124/full*). Officials of the UNOS have stated at public meetings that in their judgment up to 1,000 kidneys of the approximately 3,000 that are discarded each year are of good enough quality to be transplanted successfully. The number of organ transplantations reached record highs in 2016 (33,500), about 20 percent more than 5 years earlier, due mainly to increased donation rates (OPTN, ''United States organ transplants and deceased donors set new records in 2016.'' Accessed at *https://optn.transplant.hrsa.gov/news/us-organ-transplants-and-deceased-donors-set-new-records-in-2016/*).

For purposes of this analysis, one approach to estimating effects is to isolate the number of kidneys (and other organs) that have been discarded as a result of the March 2007 rule; indeed, a reasonable assumption would be that this proposed rule's rescission of the 2007 requirements would have an equal and opposite effect. A slide presentation by UNOS researcher Darren Stewart (2017; accessed at *https://www.myast.org/sites/default/files/ceot2017/AST%20CEOT%2001%20*

Stewart%20-%20No%20Organ%20Left%20Behind%20-%20S3.pdf), presents an estimate that about 1,110 of about 2,759 kidneys discarded in 2012 were of transplant quality and that between 500 and 1,000 of these could have been used in transplants (the most recent discard numbers, for 2016, are about 20 percent higher than in 2012 and one-third higher than in 2007). This presentation cites the study previously discussed in this preamble (Stewart et al. (2017)), that shows kidney discard rates rising from between 5 and 7 percent in the late 1980s to 19.2 percent in 2015. Notably, the discard rate had already reached approximately 18 percent by 2007, making the rate of increase much lower after the March 2007 rule was implemented than it had been in the previous two decades. Although this contrary evidence is far from definitive, it suggests that the effect of the March 2007 rule was too small to be observable in the kidney discard data.

Unfortunately, these and other studies have had to deal with other trends during the last two decades that greatly complicate measuring the independent effect of the 2007 rule. These include the increasing age of the donor pool and the attendant decline in some dimensions of organ quality, and the opposite effects of improved techniques for maintaining organ quality between the time of donation and the time of transplantion. As a result, the published studies using data on organ discards have had to use complicated multivariate statistical procedures in attempting to estimate the effects of the 2007 rule, and invariably conclude that their findings are subject to considerable uncertainty.

The preceding analysis focuses on discard rates as a tool that transplant programs can use to reduce risk of lower patient or organ survival rates, and hence risk of closure under the 2007 rule. A second tool that a transplant program can use to reduce its risk of lower overall patient survival rates is to remove patients who are slightly less likely to survive from its waiting list, most commonly by making a judgmental decision that the patient is ''too sick for transplantation.'' Programs that are on the margin of receiving regulatory sanctions, or that have received such sanctions already, are particularly likely to exercise such judgments to reduce regulatory risk. Several studies have estimated specific numbers of transplant reductions due to the 2007 rule by comparing the number of patients removed from the waiting list at programs that have received regulatory sanctions to those that have not. To provide a baseline, these studies make the conservative assumption that those programs with zero sanctions have not removed any patients from their transplant waiting list in order to avoid sanctions. For kidneys, one study estimated that in the seven year period from 2007 to 2014, the lower performing programs removed from waiting lists over 2500 patients more than would have been expected absent sanctions, an average of over 350 per year (J.D. Schold et al., ''Association of Candidate Removals From the Kidney Transplant Waiting List and Center Performance Oversight,'' American Journal of Transplantation 2016, 1276–1284). The implications, for the present time, of wait list changes initiated in 2007 is unclear. Increased mortality in 2007 among the very sick patients who were dropped from the wait list would have freed up organs for 2007's moderately sick patients; these patients otherwise would have declined in health so as to be the very sick population in 2008. Thus the absolute level of health in 2008 would have been relatively good, in which case the phenomenon of patients being dropped from the wait list might not have perpetuated into the future, leaving little or no scope for benefits to be achieved now as a result of the proposed CoP revision. (We note that one year, from 2007 to 2008, may be an exaggeration as to the short-term nature of this wait list-related effect, but a somewhat longer tapering period could still have reached completion now, more than a decade after the implementation of the 2007 CoP, thus leaving little scope for benefits.) On the other hand, if the sickest patients in 2008 were dropped based on their relative health levels—in spite of their improved absolute health relative to the sickest patients in 2007—there would be potential wait list-related benefits from revising this CoP at the present time. The benefits of shifting transplants to the sickest patients from relatively less sick patients have not been quantified, but because the harm to the less sick patients would need to be netted off the benefit to the sickest patients, the per-transplant magnitude would be much lower than the per-transplant benefits of avoided organ discards.

Another quantitative study of kidney transplant effects used a similar methodology and estimated that as a result of the 2007 rule, in 2011 sanctioned programs performed 766 fewer kidney transplants than would otherwise have been the case (Sarah L. White et al., ''Patient Selection and Volume in the Era Surrounding Implementation of Medicare Conditions of Participation for Transplant Programs,'' Health Services Research, April 2015, 330–350). White et al.'s finding of reduced transplant volumes at particular kidney transplant centers does not necessarily indicate decreased transplant volumes overall, with the authors stating that their aggregate results ''do not indicate that the introduction of the [2007] CoPs has systematically reduced opportunities for marginal candidates or that there has been a systematic shift away from utilization of higher risk deceased donor kidneys.'' In other words, regulatory sanctions could have triggered behavioral responses by some patients, some transplant surgeons, or some health insurance plans to shift patients away from these centers (many insurers restrict coverage through ''centers of excellence'' programs). Schold et al. (2013) find additional support for this phenomenon, describing their empirical result as follows: ''Among 203 [adult kidney transplant] centers, 46 (23%) were low performing (LP) . . . Among LP centers, there was a mean decline in transplant volume of 22.4 cases compared to a mean increase of 7.8 transplants among other centers.'' The estimated decrease per low-performing transplant center is roughly three times the increase per other center, but there are also roughly three times as many other centers as low-performing centers; as such, the most straightforward interpretation of this paper is that the same number of transplants is being concentrated in a smaller number of transplant centers. This outcome could still have real impacts, such as changes in travel time for patients, but although these impacts are valid for inclusion in a regulatory impact assessment, they would be much smaller in magnitude than the longevity benefits emphasized elsewhere in this analysis.

A feature common to most of these studies that is that they use data that are already several years old when the study is published, both because of the usual publishing lag and because performance data such as one-year survival rates necessarily make transplant program results less timely. None of these studies covers the last two or three years of transplant program performance. As a result, none of these studies has been able to use actual data to assess the effects of the May 13, 2016 CMS changes that slightly reduced the performance level for finding a ''condition-level'' violation that threaten's program closure. For recent reviews of potential effects of those changes see B.L. Kasiske et al., ''Potential Implications of Recent and

Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States,'' Am J Transplant, December 2016, 16(12), 3371–3377, and Colleen Jay and Jesse Schold, ''Measuring transplant center performance: The goals are not controversial but the methods and consequences can be,'' Curr Transplant Rep, March 2017, 4(1), 52–58. Using past data to measure potential effects, these studies predict little or no positive effect from the revised standards (which both studies conclude will still mis-identify lower performing programs), but cannot evaluate actual effects because post-issuance evidence is not yet available. This may not be relevant policy-wise, since we propose to eliminate those standards, but it is a key question for estimating the remaining scope (if any) of CoP-associated unnecessary organ discards, and it does flag the pervasive problem of timeliness of data and timeliness of study findings.

There are several studies that make similar estimates for liver transplant programs (for example, L.D. Buccini, et al., ''Association Between Liver Transplant Center Performance Evaluations and Transplant Volume,'' American Journal of Transplantation 2014, 2097–2105). This study found a large difference in transplant volume between programs rated as lower performing by the SRTR (average decrease of 39.9 transplants from 2007 to 2012) and those not receiving adverse SRTR ratings (average increase of 9.3 transplants over the same period). The 27 lower performing centers thus reduced their total number of liver transplants by over 1,000, and compared to the higher performing centers the decrease was even larger. This study did not, however, tie its estimates to the performance standards in the 2007 rule (which are similar but not identical to SRTR standards), to sanctions under that rule, or to specific center decisions, such as removing candidates from the wait list. Hence, while it certainly contributes to the body of scholarship indicating that since 2007 transplants have been performed in a more concentrated set of programs, it does not appear to provide direct estimates of the quantitative effects of the 2007 rule on overall numbers of liver transplants.

Taking into account all the various uncertainties involved in these studies, we do not believe that we can estimate the effects of the 2007 rule on numbers of transplantations for any organ other than kidneys, and that even for kidneys there is no clear central estimate of likely quantitative effects. The wide variation in published results, and the disclaimers as to the various uncertainties involved, make a precise as well as reliable estimate all but impossible and would render arbitrary any non-zero lower bound estimate of health and longevity impacts. (As noted above, however, even in the absence of health and longevity effects, there may be other benefits, such as reduced travel costs, if the proposed rule reduces concentration of transplants in a smaller number of facilities.) Therefore, we have shown the effects of the proposed change as ''not quantified.'' This is not unusual in Regulatory Impact Analyses that address complex phenomena that cannot be measured directly, or whose effects are intertwined with other changing circumstances. That said, we welcome any additional information that might allow a quantitative estimate in the final rule.

Every transplant quality organ that is used for transplantation rather than discarded has a very high probability of substantially extending the life of the recipient. There is a particularly extensive literature on life expectancy before and after transplant, quality of life, and cost savings for kidney patients. A literature synthesis on ''The Cost-Effectiveness of Renal Transplantation,'' by Elbert S. Huang, Nidhi Thakur, and David O. Meltzer, in Sally Satel, *When Altruism Isn't Enough* (AEI Press, 2008) found essentially universal agreement that kidney transplants were not only substantially life extending, but also cost reducing. The authors performed an extensive literature search and found that from 1968 to 2007 seventeen studies assessed the cost-effectiveness of renal transplantation. The authors concluded that ''Renal transplantation . . . is the most beneficial treatment option for patients with end-stage renal disease and is highly cost-effective compared to no therapy. In comparison to dialysis, renal transplantation has been found to reduce costs by nontrivial amounts while improving health both in terms of the number of years of life and the quality of those years of life'' (page 31). More recent studies have reached similar conclusions, as have other syntheses. For example, the ''Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcome'' (M. Tonelli, N. Wiebe, G. Knoll, A. Bello, S. Browne, D. Jadhov, S. Klarenbach, and J. Gill, American Journal of Transplantation 2011: 2093–2109) focused on life expectancy and quality of life. This article reviewed 110 studies, and concluded that the vast majority showed major improvement in life quality and reductions in mortality among transplant recipients compared to those remaining on dialysis. The *Annual Data Report* of the United States Renal Data System utilizes national data on ESRD, and reports that deaths per 1,000 patient years are about 180 for dialysis patients and about 32 for transplant recipients (see 2016 report, volume 2, Figure i.13 and Tables H.4 and H.10; accessed at *https://www.usrds.org/adr.aspx*). There are similar data on other organs. For example, in 1998, HHS published a final rule with comment period that established governance procedures for the OPTN (63 FR 16296). In the RIA for that rule, the Department estimated that ''the annual benefits of organ transplantation include about eleven thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs'' (63 FR 16323).

Even without a robust aggregate estimate of likely increases in organ utilization as a result of this proposed regulatory change, the potential benefits are very substantial. For each new kidney transplantation, there would be an average of 10 additional life years per transplant patient compared to those on dialysis (see Wolfe A. et al., ''Comparisons of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant,'' NEJM, 1999, 341:1725–30; accessed at *http://www.nejm.org/doi/full/10.1056/NEJM199912023412303#t=article*). Valuing each year of life gained using a ''value of a statistical life year'' (VSLY) of $490,000 in 2014 dollars, the total benefits from each additional transplantation in 2018 would be $4.9 million before discounting and $4.4 million after inflating to 2016 dollars and discounting at either 3 percent over the 10-year period (life-year figure for 2014 from Office of the Assistant Secretary for Planning and Evaluation, HHS, Guidelines for Regulatory Impact Analysis, 2016, page 21, accessed at *https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis*). The HHS methodology produces the same result at either discount rate in order to reach the same predetermined ''real'' value. For an explanation and justification of this VSLY approach, see Cass R. Sunstein, ''Lives, Life-Years, and Willingness to Pay,'' 104 Columbia Law Review [i] (2004).

Those HHS guidelines also explain in some detail the concept of quality adjusted life years. The key point to understand is that these are research-based estimates of the value that people

are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY amount used in any estimate of overall benefits is not meant to be a precise estimate, but instead is a rough statistical measure that allows an overall estimate of benefits expressed in dollars.

An alternative and more sophisticated analysis would take into account that the life-extending effect of a kidney transplant is not its first effect, but typically follows a number of years off dialysis, until the organ fails and the patient returns to dialysis or is retransplanted. Such an analysis can be found in a recent study by P.J. Held et al., ''A Cost-Benefit Analysis of Government Compensation of Kidney Donors,'' American Journal of Transplantation, 2016, pages 877–885 (plus 65 pages of supplementary details explaining all assumptions, data sources, and calculations). The largest differences between the base case estimated in that study and the preceding estimates is that this RIA uses the considerably higher value of a statistical year of life under HHS guidelines, and this RIA uses the full value of a statistical life year without a ''quality'' adjustment for the added years of life (we use QALYs only for the improved quality of life during years that would otherwise be on kidney dialysis). Under such an estimation approach, potential life-extending benefits could be somewhat larger. For example, if the proposed reform increased the number of life-extending kidney transplants by only 100 a year, and the benefits of both additional life years and QALY gains were estimated at $5.1 million per patient, its total annual benefits for kidney patients would be approximately $510 million a year (100 × $5.1 million).

There are additional benefits from kidney transplantation. As previously discussed, kidney transplants do reduce medical costs, with ''breakeven'' after about 5 years and net savings of several hundred thousand dollars per patient. Other organ transplants create lesser or no medical savings because the alternative is not dialysis. Clearly, however, these kidney transplant savings are small in relation to the life-extending benefits. We have not estimated medical savings or costs for kidneys or other organs in this RIA because any such estimates would depend on the number of additional transplants that we have not estimated.

We welcome comments on the quantitative and non-quantitative portions of the preceding discussion and seek any empirical evidence that would allow robust estimates of benefits, and in particular robust quantitative estimates of the number of patients deprived of transplantation as a result of the 2007 rule, as currently implemented to reflect the 2016 guidance, for each organ type. We also welcome comments on whether we have accurately and reasonably summarized the research evidence on the effects of the 2007 rules, particularly in the light of the many other factors influencing transplantation trends and performance.

We note that life-extending estimates are averages across patients who vary widely in age, medical condition, and life expectancy, as well as type of organ failure. For example, the sickest patients typically have very low life expectancies without transplant, and hence stand to gain the most years of life from a transplant. Partly offsetting this, these same patients, on average, have slightly lower survival rates post-transplant. Organ and patient survival issues are complex and dealt with by detailed policies and procedures developed and used by the transplant community under the auspices of the OPTN. These policies are reviewed and revised frequently based on actual experience and changing technology—over time the success rate from previously marginal organs, and in older patients, have both increased substantially. For purposes of this analysis, the proper measure is the average gain across all patients who would receive transplants as a result of eliminating the 2007 rule, net of these other factors.

There could be potential offsets to these calculated and uncalculated benefits and cost reductions. However, the particular regulatory requirements we propose to remove are unlikely to drive any further significant increases in graft and patient survival. For renal transplants, the expected 1-year graft and patient survival rates are already at 95 percent or better. Transplant program outcomes will continue to be monitored by the OPTN and programs that are not in compliance with the OPTN outcomes are referred to their Membership and Professional Standards Committee for quality improvement activities. The SRTR also publishes detailed data on transplant program performance that allows patients and their physicians to compare transplant programs and this transparency creates pressures to maintain and improve survival rates in order to attract these patients.

The current regulatory requirements for transplant centers, as discussed in section II.E ''Transplant Centers'' of this proposed rule, have created both positive and adverse incentives for transplant programs, with unanticipated side effects on both utilization of donated organs and the ability of the highest risk patients to obtain transplants. We expect the proposed change to provide substantial net benefits, particularly since other regulatory and informational incentives remain in place.

We welcome comments on this analysis as well as information that would enable a more robust quantitative analysis of the impacts of this change and on any alternative reforms that might provide even higher benefits.

6. Effects on HHAs

As of May 2017 there are 12,624 HHAs that participate in Medicare and Medicaid. In the January 2017 HHA CoP final rule (82 FR 4149) we estimated that compliance with the requirements at § 484.50(a)(3) related to providing oral notice of all rights to each patient would impose a burden of 5 minutes per patient, or 330,246 hours of burden nationwide at a cost of $80,030,370, annually. The cost estimate was based on a $63 per hour estimate for the services of a RN as derived from the BLS Occupational Handbook, 2014–2015 edition, including a 100 percent benefit and overhead package. Adjusted to reflect more updated salary information, as described previously, we estimate that compliance with this provision would impose a $91,786,974 burden, based on a RN earning $69 per hour.

We propose to revise the verbal notification requirements to limit them to those that are required by section 1891 of the Act. Limiting the amount of information that is required to be provided orally will reduce the time per patient that is required to comply with the revised requirement. For purposes of this analysis only, we assume that providing oral notice regarding financial liability only will require 2 minutes per patient, reducing burden by 60 percent. Based on this assumption, this proposed change would reduce the burden of the patient rights notification requirement by 198,148 hours (330,246 hours originally estimated × 0.6) and $55,072,184 ($91,786,974 burden as updated to reflect more recent salary estimates × 0.6).

We also propose two changes that do not have a savings estimate. First, we propose to eliminate the requirement at § 484.80(h)(3) that the HHA conduct a full competency evaluation of deficient home health aides, and replace it with a requirement to retrain the aide regarding the identified deficient skill(s) and require the aide to complete a competency evaluation related to those

skills. As we stated in the January 2017 HHA CoP final rule (82 FR 4575), it is standard practice within the HHA industry to supervise home health aides, and the regulatory requirements for such supervision do not impose any additional burden.

Second, we propose to remove the requirement at § 484.110(e) related to providing a requested copy of the clinical record at the next home visit, while retaining the requirement to provide the record within 4 business days. As stated in the January 2017 HHA CoP final rule (82 FR 4568 and 4575), we believe that providing such information to patients is a usual and customary practice that does not impose a burden upon HHAs. As such, removing the ''next home visit'' timeframe requirement would not result in a savings of burden hours or dollars.

We welcome public comment regarding these burden estimates, and additional regulatory reforms to reduce the burden of the HHA CoPs.

7. Effects on CAHs

We propose to remove the requirement at § 485.627(b)(1) for CAHs to disclose to CMS its owners or those with a controlling interest in the CAH or any subcontractor in which the CAH directly or indirectly ha a 5 percent or more ownership interest in accordance with 42 CFR part 420, subpart C. We discuss the economic impact of this provision in the ICR section, which is estimated at $141,000 total for all CAHs. We discussed the burden reduction for our proposed revision of the ''patient care policies'' requirements imposed on CAHs in the ICR section of this rule, which is estimated at $2.5 million.

8. Effects on CORFs

We discussed the burden reduction for our proposed revision of the ''utilization review plan'' requirements imposed on CORFs in the ICR section of this rule, which is estimated at $309,072.

9. Effects on CMHCs

We discussed the burden reduction for our proposed revision of § 485.914(d)(1) ''update of the comprehensive assessment'' requirements imposed on CMHCs in the ICR section, which is an estimated savings of $152,464.

10. Effects on Portable X-Ray Services

At § 486.104 we propose to revise the portable x-ray CfCs to focus on the qualifications of the technologist performing the diagnostic test. As of May 2017 there were approximately 500 Medicare-participating portable x-ray suppliers employing an estimated 5,000 portable x-ray technologists. Hiring limited x-ray technologists or those with State licensure would allow portable x-ray suppliers to fill vacant positions at a lower hourly cost. Assuming a 10 percent annual turnover rate, all technologists could be hired at the lower salary over a period of 10 years. Limited x-ray technologists can be hired for approximately $30 an hour ($62,400 per year), whereas, according to the BLS, x-ray technologists with advanced certification (ARRT) are hired at a rate of approximately $60 dollars per hour ($124,800 per year). This creates a savings opportunity of $30 per hour, or $62,400 per year, per technologist position. Based on an assumed 10 percent turnover rate, or 500 positions filled in any given year, this change would create a savings of $31,200,000 savings in the first year. We believe that these savings would be increased every year as more positions are filled at the lower salary rate.

We welcome public comment regarding these burden estimates, and additional regulatory reforms to reduce the burden of the portable x-ray CfCs.

11. Effects on RHCs and FQHCs

We discussed the burden reduction for our proposed revision of § 491.9(b)(4) ''review of patient care policies'' requirements imposed on RHCs and FQHCs in the ICR section, which is an estimated savings of $6.8 million. In addition, the burden reduction for our proposed revision of § 491.11(a) ''program evaluation'' requirements imposed on RHCs and FQHCs in the ICR section of this rule, which is an estimated savings of $9.4 million.

12. Effects of Emergency Preparedness Requirements on Providers and Suppliers

This proposed rule revises the emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers, as discussed in detail in section II.M of this proposed rule. The proposed modifications to the emergency preparedness requirements either simplify the requirements, eliminate duplicative requirements, or reduce the frequency in which providers would need to comply with the emergency preparedness requirements. We estimate that the proposed changes to the emergency preparedness requirements would accrue an annual cost savings of $155 million in total. The potential, estimated cost savings for each revised emergency preparedness requirement is outlined in detail below. The methodology used to calculate the economic impact and the costs associated with the proposed changes to the emergency preparedness requirements is the same methodology used to calculate the economic impact in the Emergency Preparedness final rule (81 FR 63860).

At § 482.15(a), (b), (c), and (d) for hospitals and parallel regulatory citations for other facilities, we propose to allow providers to review their program at least every 2 years. We discuss the economic impact for this requirement in the ICR section of this rule, which represents $94,312,719 in savings.

At § 482.15(a)(4) for hospitals, and other parallel citations for the facilities mentioned in section II.J.2 of this proposed rule, we propose to eliminate the requirement that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and that facilities document participation in collaborative and cooperative planning efforts. We discuss the economic impact for this requirement in the ICR section of this rule, which represents $7,179,117 in savings.

At § 482.15(d)(1)(ii) for hospitals, and other parallel citations for other facilities mentioned in section II.J.2 of this proposed rule, we propose to require that facilities provide training biennially, or every 2 years, after facilities conduct initial training on their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated. We discuss the economic impact for this requirement in the ICR section of this rule, which represents $33,267,864 in savings. Finally, at § 482.15(d)(2), we propose to require that providers of inpatient services mentioned in section II.J.2 of this proposed rule conduct two testing exercises annually, one of which may be an exercise of their choice that must be either a community-based full-scale exercise (if available), an individual facility-based functional exercise, a drill, a tabletop exercise or workshop that includes a group discussion led by a facilitator. We propose to require that providers of outpatient services mentioned in section II.J.2 of this proposed rule conduct one testing exercise annually which must be either a community-based full-scale exercise (if available) or an individual facility-based functional exercise every other year, and in the opposite years, may be either a community-based full-scale exercise (if available), a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. We

discuss the majority of this economic impact for this requirement in the ICR section, which represents $9,117,425 in savings. We do not estimate any economic impact for the providers of inpatient services as we are not proposing any changes to the number of testing exercises that must be conducted by these providers; however, we estimate an additional economic impact for this provision for each outpatient provider due to a reduction in the testing requirement from two exercises per year to one exercise per year. We would like to note that for CORFs and Organizations, consistent with the Emergency Preparedness Final Rule (*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Final Rule,* 81 FR 63860), the CoPs for these providers previously required them to have ongoing drills and exercises to test their disaster plans. Therefore, we continue to expect, as we did in the Emergency Preparedness final rule, that the economic impact to comply with this requirement will be minimal, if any. Therefore, the total economic impact of this provision for CORFs and Organizations will be limited to the estimated ICR burden of $55,272 and $305,172, respectively.

We estimate a total impact savings of $10,997,373 for this proposed change. With an estimated ICR savings of $9,117,425, we estimate that the total economic impact of this rule for the affected providers will be $20,114,798. We list a summary of the calculation for the impact savings accrued by removing this requirement for each facility in Table 15, based on facility numbers available as of May 2017.

- *ASCs:* Combined total savings of $1,967,178 for 5,557 ASCs ((4 hours for an administrator at $108 per hour plus 4 hours for a registered nurse at $69 per hour) × 5,557 ASCs × 50 percent).
- *Outpatient Hospice:* Combined total savings of $1,405,920 ((4 hours for an administrator at $105 per hour plus 4 hours for a registered nurse at $69 per hour) × 4,040 outpatient hospices × 50 percent).
- *PACE:* Combined total savings of $16,077 ((1 hour home for a care coordinator at $69 per hour plus 1 hour for a quality improvement nurse at $69) × 233 PACEs × 50 percent).
- *HHAs:* Combined total savings of $2,632,104 ((2 hours for an administrator at $105 per hour plus 3 hours for a director of training at $69 per hour) × 12,624 HHAs × 50 percent).
- *CMHCs:* Combined total savings of $58,926 ((5 hours for an administrator at $105 per hour plus 3 hours for a nurse at $69 per hour) × 161 CMHCs × 50 percent).
- *OPOs:* Combined total savings of $5,046 ((1 hour for a QAPI Director at $105 per hour plus 1 hour for an education coordinator at $69 per hour) × 58 OPOs × 50 percent).
- *RHCs/FQHCs:* Combined total savings of $ 4,187,832 (((4 hours for an administrator at $105 per hour plus 4 hours for a registered nurse at $69 per hour) × 4,160 RHCs × 50 percent) plus (4 hours for an administrator at $105 per hour plus 4 hours for a registered nurse at $69 per hour) × 7,874 FQHCs × 50 percent).
- *ESRDs:* Combined total savings of $724,290 ((1 hour for an administrator at $105 per hour plus 1 hour for a nurse manager at $105 per hour) × 6,898 dialysis facilities × 50 percent).

TABLE 15—COST SAVINGS FOR EMERGENCY PREPAREDNESS TESTING

Provider/supplier	Cost savings per provider/ supplier	Combined total savings
ASCs	$354	$1,967,178 for 5,557 ASCs.
Hospices (outpatient)	348	$1,405,920 for 4,040 outpatient hospice facilities.
PACEs	69	$16,077 for 233 PACEs.
HHAs	209	$2,632,104 for 12,624 HHAs.
CMHCs	366	$58,926 for 161 CMHCs.
OPOs	87	$5,046 for 58 OPOs.
RHCs/FQHCs	348	$4,187,832 for RHCs and FQHCs ($1,447,680 for 4,160 RHCs and $2,740,152 for 7,874 FQHCs).
ESRD Facilities	105	$724,290 for 6,898 dialysis facilities.

13. One-Time Implementation Costs

All of the changes presented above will necessarily have to be read, and understood, and implemented by affected providers. This will create one-time costs even though the underlying change reduces burden. In most cases these costs will be very low, and may be as simple as observing that a particular procedure will need only to be performed once rather than twice a year, and changing the schedule accordingly. In some cases, the facility will need to adjust in response to multiple burden reduction changes. In still other cases, time will have to be spent deciding how to change existing policy. For example, as discussed previously, ASCs and hospital outpatient facilities will need to decide whether and in what circumstances medical histories and physical examinations will be required or encouraged as a matter of policy. Rather than attempt to estimate these situational variables in detail for each facility type, we believe it possible to make reasonable overall estimates of these one-time costs, recognizing that there will be considerable variations among provider types and among individual providers.

In total, there are about 122 thousand affected entities, as shown in the Table 17 that follows. We assume that on average there will be 1 hour of time spent by a lawyer, 2 hours of time by an administrator or health services manager, and 2 hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further estimate that for one tenth of these providers, 2 hours of physician time will be needed to consider changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are $134 for lawyers, $105 for managers, $70 for registered nurses, and $198 for physicians. These numbers are from BLS statistics for 2016, at *https://www.bls.gov/oes/2016/may/oes_nat.htm.*

The estimated costs for an average provider would therefore be 1 hour at $134 and in total for the lawyers, 2 hours at $105 or $210 in total for the managers, 2 hours at $69 or $138 in total for the other staff, and two-tenths of 1

hour at $198 or $40 in total for the physicians. These one-time costs add up to $522 per provider on average, and in total to about $64 million.

TABLE 16—ONE-TIME IMPLEMENTATION COSTS

Provider type	Number of affected providers
Religious Nonmedical Health Care Institutions	18
Ambulatory Surgical Centers and hospital outpatient	10,587
Hospices	4,602
Hospitals	5,031
Transplant programs	750
Home Health Agencies	12,624
Critical Access Hospitals	1,343
Comprehensive Outpatient Rehabilitation Facilities	188
Community Mental Health Centers	52
Portable X-Ray Services	500
Rural Health Clinics and Federally Qualified Health Centers	12,034
Emergency Preparedness of Providers and Suppliers	74,246
Total Number of Providers	122,180
Average Cost Per Provider	$522
Total One-Time Cost	$63,777,960

13. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all health care providers regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year, varying by type of provider and highest for hospitals). Accordingly, almost all of the savings that this proposed rule would create will benefit small entities. We note that individual persons are not small entities for purposes of the RFA, and hence the life-extending transplantation benefits of the proposed rule are not relevant to the RFA.

The RFA requires that a Regulatory Flexibility Analysis (RFA) be prepared if a proposed rule would have a ''significant impact on a substantial number'' of such entities. HHS interprets the statute as mandating this analysis only the impact is adverse, though there are differing interpretations. Regardless, there is no question that this proposed rule would affect a ''substantial number'' of small entities. As shown in Table 17, the total number of affected entities will be about 122,000, including those affected by more than one provision. The rule of thumb used by HHS for determining whether an impact is ''significant'' is an effect of 3 percent or more of annual revenues. These savings do not approach that threshold. Hospitals account for about one-third of all health care spending and even if all these savings accrued to hospitals this threshold would not be approached. Therefore, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. For the reasons previously given, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $148 million. This proposed rule contains no mandates that will impose spending costs on State, local, or tribal governments, or on the private sector. Indeed, it substantially reduces existing private sector mandates.

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 requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule imposes no such requirements. Importantly, it would remove Federal requirements setting qualification standards for hospice aides. Setting qualifications for health care workers is traditionally a State function, and this change would therefore remove an infringement on State prerogatives.

14. Effects on Costs to Facilities, Providers, Medicare, Other Insurance, and Patients

Most of the individual proposals addressed in the preceding analysis involve reducing burdensome costs on facilities, health care professionals, and patients. Most of those reductions save time and effort currently performed on tasks that we propose to eliminate or reform and those reductions will result ultimately in reduced medical care costs in these facilities, some of which will result in further effects on public and private insurance costs. In this regard, it is important to emphasize that the CoPs and CfCs generally apply to all patients served by a Medicare and/or Medicaid participating provider or supplier, not just Medicare or Medicaid patients, and

to the entire operations of the provider. Revisions to those requirements apply broadly to the entire health care system. We are hopeful that cost reductions ultimately flow to reductions in charges, to reductions in third party payments, and hence to reductions in insurance costs and to those who pay those costs.

In total, we estimate that the approximately 40 specific provisions summarized in Tables 1 and 2 that are not related to reductions in pre-operative physical examinations and tests in outpatient surgery, or to transplantation, will save facilities and other providers, insurers, and patients about $669 million annually. The initial savings will accrue primarily to providers. How much of these savings will flow to insurers and patients depends primarily on the payment and reimbursement mechanisms in place for each affected entity for those particular costs. According to the National Health Expenditure Accounts, approximate payer shares in 2016 were 11 percent for consumer out of pocket, 35 percent for private health insurance, 21 percent for Medicare, 18 percent for Medicaid, and 15 percent for other public and private payers such as the Department of Veteran Affairs and the Department of Defense. We would expect savings to approximate these shares. Ultimately, all costs are paid by workers and taxpayers who pay for all health care directly or indirectly, quite apart from immediate cost subsidies or cost sharing.

Two provisions directly reduce Medicare and other insurance costs. Eliminating unnecessary patient history and physical examinations and medical tests for procedures (such as cataract surgery) performed in ASCs and in hospital outpatient surgery will disproportionately reduce Medicare costs, since use of these services rises with age. Additional transplantation of kidneys will reduce Medicare's ESRD costs, partially offset by increased transplantation costs. Because of the difficulty in finding evidence of the volume of such savings, we cannot estimate the likely effects on Medicare spending.

Most of the facility and provider savings will accrue to Medicare and other insurers over time as payment rate increases are slightly reduced, and the remainder will accrue to other payers and to patients.

The following table shows our estimates of savings by major burden reduction category and by type of payer.

TABLE 17—SAVINGS BY MAJOR PAYER CATEGORIES

[$ Millions]

Savings to:	Ambulatory surgery	Transplant programs	All other cost reductions	Total
Medicare	123	not estimated	141	264
Medicaid	57	not estimated	120	177
Private Insurance	110	not estimated	234	344
Other Payers	47	not estimated	100	147
Patients	117	not estimated	74	191
Total	454	not estimated	669	1,123

Note: Calculations based largely on payer percentages in ''National Health Care Spending in 2016,'' Health Affairs, January 2018, pages 150–160. Patient share for ambulatory surgery savings reflects travel time, not medical costs.

15. Benefits to Patients

We discussed life-extending and life-saving benefits at length in the analysis of increases in transplantation. These result from removal of disincentives to transplant patients, or to use organs, where this could reduce success rates by a few percent and possibly trigger closure of transplant centers or programs under current rules. As previously explained, we do not have robust estimates. There are additional and substantial patient benefits likely to result from the cost-reducing reforms that we propose. Time not wasted by medical care providers or facilities on unnecessary tasks is time that can be used to focus on better care. While such effects could be measured in principal, there is little existing data on magnitudes of such effects. We do, however, welcome public comments on these or any other aspects of costs and benefits of the proposed rule.

D. Alternatives Considered

From within the entire body of CoPs and CfCs, we selected what we believe to be the most viable candidates for reform as identified by stakeholders, by recent research, or by experts as unusually burdensome. This subset of the universe of standards is the focus of this proposed rule. For all of the proposed provisions, we considered not making these changes. Ultimately, we saw no good reasons not to propose these burden reducing changes.

We welcome comments on whether we properly selected the best candidates for change, and welcome suggestions for additional reform candidates from the entire body of CoPs and other regulatory provisions that fall directly on providers.

E. Uncertainty

Our estimates of the effects of this regulation are subject to significant uncertainty. While the Department is confident that these reforms will provide flexibilities to facilities that will yield major cost savings, there are uncertainties about the magnitude of these effects. Despite these uncertainties, we are confident that the rule will yield substantial overall cost reductions and other benefits. In this analysis we have provided estimates to suggest the potential savings these reforms could achieve under certain assumptions. We appreciate that those assumptions are simplified, and that actual results could be substantially higher or lower. Although there is uncertainty concerning the magnitude of all of our estimates, we do not have the data to provide specific estimates for each reform proposed, as to the range of possibilities, or to estimate all categories of possible benefits, including health effects.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 18, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

While most provisions of the proposed rule have clearly predictable effects we do not in most cases have detailed empirical information on the precise magnitude of efforts involved (for example, time spent in meeting paperwork or other administrative tasks

that apply to a particular provider type). Other provisions (notably those related to organ transplantation and removal of strict H & P requirements before ambulatory surgery) have even more uncertain effect sizes. Therefore, we have estimated an upper and lower level for benefit and cost reduction estimates that is 25 percent higher or lower than our primary estimate for all quantified reforms other than those related to ambulatory surgery, and in that area our lower bound is zero cost reductions and our upper bound is a 50% reduction in H&P and associated laboratory testing costs.

TABLE 18—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS AND SAVINGS

[$ Millions]

Category	Primary estimate	Lower bound	Upper bound	Units		
				Year dollars	Discount rate (%)	Period covered
Life-Extending Benefits (monetized)	Not Quantified					
Medical Cost Reduction Benefits (monetized)	Not Quantified					
Other Cost Reductions (monetized)	−$1,240 −$1,250	−$580 −$590	−$1,890 −$1,900	2016 2016	7 3	2018 onward. 2018 onward.
Costs	None					
Transfers	None					

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule will, if finalized as proposed, be considered an E.O. 13771 deregulatory action. We estimate that this rule generates $1,051 million in annualized cost savings, discounted at 7 percent relative to year 2018, over a perpetual time horizon. This estimate is based on cost reductions starting at $1,123 million, and growing by $31 million annually due to salary savings from X-ray technician turnover, partially offset by one-time first-year implementation costs of $64 million, all in 2016 dollars. Details on the estimated cost savings from this rule can be found in the preceding analysis. We note that public comments and additional information may enable us to estimate considerably larger savings from reforming H & P requirements for ambulatory surgery or to narrow the uncertainty within the range of the preliminary estimates.

H. Conclusion

This proposed rule would substantially reduce existing regulatory requirements imposed on health care providers through the CoPs and related regulatory provisions that Medicare and Medicaid providers must meet. For some provisions, health benefits to patients will be substantial and direct. Other provisions will free up time and efforts of health care providers to focus on improving health care quality and service delivery. Although this proposed rule does not require an Initial Regulatory Flexibility Analysis, this regulatory impact analysis, together with the remainder of this preamble, meets the requirements for such an analysis. Furthermore, the analysis in this section of the preamble, together with the remainder of this preamble, provides a complete Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing home, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedures, Health facilities, Health professions, Medicare, reporting and recordkeeping requirements.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare,

Reporting and recordkeeping requirements, Rural and Urban areas.

42 CFR Part 494

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b-3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 403.736 is amended by—
■ a. Removing the introductory text;
■ b. Revising paragraph (a);
■ c. Removing paragraph (b); and
■ d. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c).

The revision reads as follows:

§ 403.736 Condition of participation: Discharge planning.

(a) *Discharge planning and instructions.* The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. The RNHCI must assess the need for a discharge plan for any patient likely to suffer adverse consequences if there is no planning.

(1) Discharge instructions must be provided at the time of discharge to the patient or the patient's caregiver as necessary.

(2) If the patient assessment indicates a need for a discharge plan, the discharge plan must include instructions on post-RNHCI care to be used by the patient or the caregiver in the patient's home, as identified in the discharge plan.

(3) If the RNHCI's patient assessment does not indicate a need for a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.

* * * * *

■ 3. Section 403.748 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii); and
■ b. Adding paragraph (d)(1)(v).

The revisions and addition read as follows:

§ 403.748 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The RNHCI must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The RNHCI must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The RNHCI must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the RNHCI must conduct training on the updated policies and procedures.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 4. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273)).

§ 416.41 [Amended]

■ 5. Section 416.41 is amended by removing paragraph (b)(3).

■ 6. Section 416.47 is amended by revising paragraph (b)(2) to read as follows:

§ 416.47 Condition for coverage—Medical records.

* * * * *

(b) * * *

(2) Significant medical history and results of physical examination (as applicable).

* * * * *

■ 7. Section 416.52 is amended by revising the section heading and paragraph (a) to read as follows:

§ 416.52 Condition for coverage—Patient admission, assessment and discharge.

* * * * *

(a) *Standard: Patient assessment and admission.* (1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must—

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: Patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Follow nationally recognized standards of practice and guidelines, and applicable State and local health and safety laws.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.

(4) The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.

* * * * *

■ 8. Section 416.54 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 416.54 Condition for coverage—Emergency preparedness.

* * * * *

(a) *Emergency plan.* The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The ASC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The ASC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and procedures.

(2) *Testing.* The ASC must conduct exercises to test the emergency plan at least annually. The ASC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, individual, a facility-based functional exercise every 2 years. If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

* * * * *

PART 418—HOSPICE CARE

■ 9. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 10. Section 418.76 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 418.76 Condition of participation: Hospice aide and homemaker services.

* * * * *

(a) * * *

(1) * * *

(iv) A State licensure program.

* * * * *

■ 11. Section 418.106 is amended by—

■ a. Removing paragraph (a)(1);

■ b. Redesignating paragraph (a)(2) as paragraph (a)(1);

■ c. Adding a new reserved paragraph (a)(2); and

■ d. Revising paragraph (e)(2)(i).

The revision reads as follows:

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

* * * * *

(a) * * *

(2) [Reserved]

* * * * *

(e) * * *

(2) * * *

(i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management, use, storage, and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:

(A) Provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative and family in a format that is available on a continual basis;

(B) Discuss the information regarding the safe use, storage and disposal of controlled drugs with the patient or representative, and the family, in a language and manner that they understand to ensure that these parties are effectively educated; and

(C) Document in the patient's clinical record that the information was provided and discussed.

* * * * *

■ 12. Section 418.112 is amended by adding paragraph (c)(10) and removing paragraph (f) to read as follows:

§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID.

* * * * *

(c) * * *

(10) A delineation of responsibilities for assuring orientation of SNF/NF or ICF/IID staff furnishing care to hospice patients, to include information regarding the hospice philosophy; hospice policies and procedures regarding methods of comfort, pain control, and symptom management; principles about death, dying, and individual responses to death; patient rights; appropriate forms; and record keeping requirements.

* * * * *

■ 13. Section 418.113 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(iii);

■ b. Adding paragraph (d)(1)(vi);

■ c. Revising paragraph (d)(2); and

■ d. Adding paragraph (d)(3).

The revisions and addition to read as follows:

§ 418.113 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal,

regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The hospice must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The hospice must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(iii) Provide emergency preparedness training at least every 2 years.

* * * * *

(vi) If the emergency preparedness policies and procedures are significantly updated, the hospice must conduct training on the updated policies and procedures.

(2) *Testing for hospices that provide care in the patient's home.* The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(3) *Testing for hospices that provide inpatient care directly.* The hospice must conduct exercises to test the emergency plan twice per year. The hospice must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the hospice's emergency plan, as needed.

* * * * *

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 14. The authority citation for part 441 continues to read as follows:

Authority: Secs. 1102, 1902, and 1928 of the Social Security Act (42 U.S.C. 1302).

■ 15. Section 441.184 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 441.184 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The PRTF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The PRTF must develop and maintain an emergency preparedness training program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) After initial training, provide emergency preparedness training every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.

(2) *Testing.* The PRTF must conduct exercises to test the emergency plan

twice per year. The PRTF must do the following:

(i) Participate in a full-scale exercise annually that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PRTF's emergency plan, as needed.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 16. The authority citation for part 460 continues to read as follows:

Authority: Secs: 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

■ 17. Section 460.84 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 460.84 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The PACE organization must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The PACE organization must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at lease every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.

(2) *Testing.* The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 18. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 19. Section 482.15 is amended—
■ a. By revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. By adding paragraph (d)(1)(v);
■ c. By revising paragraph (d)(2);
■ d. In paragraph (g) introductory text, by removing the phrase ''transplant centers'' and adding into its place the phrase ''transplant programs''; and
■ e. In paragraphs (g)(1) and (2), by removing the phrase ''transplant center'' and adding into its place the phrase ''transplant program''.

The revisions and addition read as follows:

§ 482.15 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to

maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the hospital must conduct training on the updated policies and procedures.

(2) *Testing.* The hospital must conduct exercises to test the emergency plan at least twice per year. The hospital must do all of the following:

(i) Participate in an annual full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

* * * * *

■ 20. Section 482.21 is amended by adding paragraph (f) to read as follows:

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(f) *Standard: Unified and integrated QAPI program for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

■ 21. Section 482.22 is amended by—

■ a. Revising paragraphs (c)(5)(i) and (ii);

■ b. Adding paragraphs (c)(5)(iii), (iv), and (v); and

■ c. Removing paragraph (d).

The revisions and additions read as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(c) * * *

(5) * * *

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(5)(iii) of this section. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(5)(iii) of this section. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iii) An assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iv) The medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.

(v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:

(A) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure.

(B) Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures.

(C) Applicable state and local health and safety laws.

* * * * *

■ 22. Section 482.24 is amended by revising paragraphs (c)(4)(i)(A) and (B) and adding paragraph (c)(4)(i)(C) to read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * * *

(c) * * *

(4) * * *

(i) * * *

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(4)(i)(C) of this section. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(4)(i)(C) of this section. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(C) An assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) of this section) completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

* * * * *

■ 23. Section 482.42 is amended by adding paragraph (c) to read as follows:

§ 482.42 Condition of participation: Infection control.

* * * * *

(c) *Standard: Unified and integrated infection control program for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated infection control program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated infection control program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

(2) The unified and integrated infection control program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection control program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control has been designated at the hospital as responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control as directed by the unified infection control program, and for providing infection prevention education and training to hospital staff.

■ 24. Section 482.51 is amended by revising paragraphs (b)(1)(i) and (ii) and adding paragraph (b)(1)(iii) to read as follows:

§ 482.51 Condition of participation: Surgical services.

* * * * *

(b) * * *

(1) * * *

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, and except as provided under paragraph (b)(1)(iii) of this section.

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (b)(1)(iii) of this section.

(iii) An assessment of the patient must be completed and documented after registration (in lieu of the requirements of paragraphs (b)(1)(i) and (ii) of this section) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

* * * * *

■ 25. Section 482.58 is amended by—

■ a. Revising paragraph (b)(1);

■ b. Removing paragraph (b)(4);

■ c. Redesignating paragraphs (b)(5) through (8) as paragraphs (b)(4) through (7); and

■ d. Revising newly redesignated paragraphs (b)(4) and (7).

The revisions read as follows:

§ 482.58 Special requirements for hospital providers of long-term care services ("swing-beds").

* * * * *

(b) * * *

(1) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (h), (g)(8) and (17), and (g)(18) introductory text of this chapter).

* * * * *

(4) Social services (§ 483.40(d) of this chapter).

* * * * *

(7) Dental services (§ 483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

■ 26. Section 482.61 is amended by revising paragraph (d) to read as follows:

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

* * * * *

(d) *Standard: Recording progress.* Progress notes must be recorded by the physician(s), psychologists, or other licensed independent practitioner(s) responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

* * * * *

§ 482.68 [Amended]

■ 27. Section 482.68 is amended—

■ a. In the section heading by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs''; and

■ b. In the introductory text and in paragraph (b) by removing the phrase ''transplant center'' and adding in its place the phrase ''transplant program''.

■ 28. Section 482.70 is amended—

■ a. In the definition of ''Adverse event'' by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs'';

■ b. By removing the definitions of ''Heart-Lung transplant center'' and ''Intestine transplant center'';

■ c. By adding the definitions of ''Heart-Lung transplant program'' and ''Intestine transplant program'' in alphabetical order;

■ d. By removing the definitions of ''Pancreas transplant center'' and ''Transplant center'';

■ e. By adding the definition of ''Pancreas transplant program'' in alphabetical order; and

■ f. By revising the definition of ''Transplant program''.

The additions and revision read as follows:

§ 482.70 Definitions.

* * * * *

Heart-Lung transplant program means a transplant program that is located in a hospital with an existing Medicare-approved heart transplant program and an existing Medicare-approved lung program that performs combined heart-lung transplants.

Intestine transplant program means a Medicare-approved liver transplant program that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

* * * * *

Pancreas transplant program means a Medicare-approved kidney transplant program that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

* * * * *

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

§§ 482.72, 482.74, 482.78, and 482.80 [Amended]

■ 29. In the following table, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column each time it appears and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 482.72		transplant center	transplant program.
§ 482.74	(a) introductory text	transplant center	transplant program.
§ 482.74	(a) introductory text	center's	hospital's.
§ 482.74	(a)(1)	transplant center	transplant program.
§ 482.74	(a)(1)	center's	program's.
§ 482.74	(a)(2)	transplant center	transplant program.
§ 482.74	(a)(3)	transplant center	transplant program.
§ 482.74	(b) introductory text	transplant center	transplant program.
§ 482.78	Section heading	transplant centers	transplant programs.
§ 482.78	Introductory text	transplant center	transplant program.
§ 482.78	(a)	transplant center	transplant program.
§ 482.78	(b)	transplant center	transplant program.
§ 482.80	Section heading	transplant centers	transplant programs.
§ 482.80	Introductory text	transplant centers	transplant programs.
§ 482.80	(a)	transplant center	transplant program.
§ 482.80	(a)	beneficiary	recipient.
§ 482.80	(b)	transplant center	transplant program.
§ 482.80	(c) introductory text	center	program.
§ 482.80	(c)(1)	transplant center's	transplant program's.
§ 482.80	(c)(1)	center-specific report	program-specific report.
§ 482.80	(c)(1)	Beneficiaries	Recipients.
§ 482.80	(c)(2)	center's	program's.
§ 482.80	(d)(1)	transplant center	transplant program.
§ 482.80	(d)(2)	transplant center	transplant program.
§ 482.80	(d)(3)	transplant center	transplant program.
§ 482.80	(d)(4)	transplant center	transplant program.
§ 482.80	(d)(5)	transplant center	transplant program.

§ 482.82 [Removed]

■ 30. Section 482.82 is removed.

§§ 482.90, 482.92, 482.94, 482.96, 482.98, 482.100, and 482.102 [Amended]

■ 31. In the following table, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column each time it appears and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 482.90	Introductory text	transplant center	transplant program.
§ 482.90	Introductory text	center	program.
§ 482.90	(a)(2)	transplant center	transplant program.
§ 482.90	(a)(4)	transplant center	transplant program.
§ 482.90	(b) introductory text	Transplant centers	Transplant programs.
§ 482.92	Introductory text	donor-beneficiary	donor-recipient.
§ 482.92	Introductory text	beneficiary	recipient.
§ 482.92	Introductory text	Transplant centers	Transplant programs.
§ 482.92	Introductory text	transplant center	transplant program.
§ 482.92	(a)	transplant center	transplant program.
§ 482.92	(a)	beneficiary	recipient.
§ 482.92	(b)	beneficiary	recipient.
§ 482.92	(b)	beneficiary's	recipient's.
§ 482.94	Introductory text	Transplant centers	Transplant programs.
§ 482.94	Introductory text	transplant center	transplant programs.
§ 482.94	Introductory text	the center also	the program also.
§ 482.94	(a) introductory text	transplant center's	transplant program's.
§ 482.94	(a)(2)	center	program.
§ 482.94	(b) introductory text	Transplant centers	Transplant programs.
§ 482.94	(b)(2)	center's	program's.
§ 482.94	(b)(3)	center's	program's.
§ 482.94	(c) introductory text	Transplant centers	Transplant programs.
§ 482.94	(c) introductory text	center's waiting list	program's waiting list.
§ 482.94	(c)(2)	transplant center	transplant program.
§ 482.94	(c)(3) introductory text	transplant centers	transplant programs.
§ 482.94	(d) introductory text	transplant center	transplant program.
§ 482.94	(d)(2)	transplant center	transplant program.
§ 482.94	(e)	Transplant centers	Transplant programs.
§ 482.96	Introductory text	Transplant centers	Transplant programs.
§ 482.96	(a)	transplant center's	transplant program's.
§ 482.96	(a)	beneficiary	recipient.
§ 482.96	(a)	transplant center	transplant program.
§ 482.96	(b) introductory text	transplant center	transplant program.
§ 482.96	(b)(2)	transplant center	transplant program.
§ 482.96	(b)(2)	transplant center's	transplant program's.
§ 482.98	Introductory text	transplant center	transplant program.
§ 482.98	Introductory text	the center	the program.
§ 482.98	(a) (a) heading and introductory text	transplant center	transplant program.
§ 482.98	(a)(1)	transplant center	transplant program.
§ 482.98	(b) introductory text	transplant center	transplant program.
§ 482.98	(c) introductory text	transplant center	transplant program.
§ 482.98	(c)(2)	transplant center	transplant program.
§ 482.98	(d) introductory text	transplant center	transplant program.
§ 482.98	(d) heading	living donor advocate team	independent living donor advocate team.
§ 482.98	(d)(1)	living donor advocate	independent living donor advocate.
§ 482.98	(d)(2) introductory text	living donor advocate team	independent living donor advocate team.
§ 482.98	(d)(3) introductory text	living donor advocate team	independent living donor advocate team.
§ 482.98	(e)	transplant center	transplant program.
§ 482.98	(f)	transplant center	transplant program.
§ 482.100		transplant center	transplant program.
§ 482.102	Introductory text	transplant center	transplant program.
§ 482.102	(a) introductory text	Transplant centers	Transplant programs.
§ 482.102	(a)(8)	transplant center	transplant program.
§ 482.102	(a)(8)	beneficiary's	recipient's.
§ 482.102	(b) introductory text	Transplant centers	Transplant programs.
§ 482.102	(b)(1)	transplant center	transplant program.
§ 482.102	(b)(4)	beneficiary	recipient.
§ 482.102	(b)(6)	transplant center-specific	transplant program-specific.
§ 482.102	(b)(6)	beneficiaries	receipients.
§ 482.102	(b)(6)	center-specific outcomes	transplant-specific outcomes.
§ 482.102	(b)(9)	transplant center	transplant program.
§ 482.102	(b)(9)	beneficiary's	recipient's.
§ 482.102	(c) introductory text	Transplant centers	Transplant programs.
§ 482.102	(c) introductory text	center's	program's.
§ 482.102	(c) introductory text	center	program.
§ 482.102	(c)(1) introductory text	transplant center	transplant program.

Section	Paragraphs	Remove	Add
§ 482.102	(c)(1) introductory text	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(i)	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(i)	transplant center	transplant program.
§ 482.102	(c)(2)(ii)	beneficiaries	recipients.
§ 482.102	(c)(2)(ii)	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(ii)	the center	the program.
§ 482.102	(c)(2)(ii)	center's termination of approval	program's termination of approval.
§ 482.102	(c)(3)	transplant center's	transplant program's.
§ 482.102	(c)(3)	the center	the program.
§ 482.102	(c)(3)	center's waiting list	program's waiting list.
§ 482.102	(c)(3)	transplant center	transplant program.

■ 32. Section 482.102 is further amended by revising paragraph (a)(5) to read as follows:

§ 482.102 Condition of participation: Patient and living donor rights.

* * * * *

(a) * * *

(5) National and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;

* * * * *

§ 482.104 [Amended]

■ 33. For § 482.104, in the following table, for the heading and each paragraph indicated in the first column, remove the phrase indicated in the second column each time it appears and add the reference indicated in the third column:

Paragraphs	Remove	Add
Section heading	transplant centers	transplant programs.
(a)	transplant centers	transplant programs.
(a)	transplant center	transplant program.
(b)	transplant centers	transplant programs.
(c)	transplant centers	transplant programs.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 34. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

■ 35. Section 483.73 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 483.73 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The LTC facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The LTC facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the LTC facility must conduct training on the updated policies and procedures.

(2) *Testing.* The LTC facility must conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in an annual full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by

a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

* * * * *

■ 36. Section 483.475 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 483.475 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include the following:

* * * * *

(d) *Training and testing.* The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(i).

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the ICF/IID must conduct training on the updated policies and procedures.

(2) *Testing.* The ICF/IID must conduct exercises to test the emergency plan at least twice per year. The ICF/IID must do the following:

(i) Participate in an annual full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise annually. If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 37. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 38. Section 484.50 is amended by removing and reserving paragraph (a)(3) and revising paragraph (c)(7) introductory text to read as follows:

§ 484.50 Condition of participation: Patient rights.

* * * * *

(c) * * *

(7) Be advised, orally and in writing, of—

* * * * *

■ 39. Section 484.80 is amended by revising paragraph (h)(3) to read as follows:

§ 484.80 Condition of participation: Home health aide services.

* * * * *

(h) * * *

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation related to the deficient skill(s).

* * * * *

■ 40. Section 484.102 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, and (d) introductory text and the first paragraph (d)(1)(ii);
■ b. Redesignating the second paragraph (d)(1)(ii) as paragraph (d)(1)(iv);
■ c. Adding paragraph (d)(1)(v); and
■ d. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 484.102 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The HHA must develop and maintain an

emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the HHA must conduct training on the updated policies and procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

* * * * *

■ 41. Section 484.110 is amended by revising paragraph (e) to read as follows:

§ 484.110 Condition of participation: Clinical records.

* * * * *

(e) *Standard: Retrieval of clinical records.* A patient's clinical record (whether hardcopy or electronic form) must be made available to a patient, free of charge, upon request within 4 business days.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 42. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 43. Section 485.66 is amended by revising the introductory text to read as follows:

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented annually, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

* * * * *

■ 44. Section 485.68 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 485.68 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

* * * * *

(b) *Policies and procedures.* The CORF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The CORF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The CORF must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the CORF must conduct training on the updated policies and procedures.

(2) *Testing.* The CORF must conduct exercises to test the emergency plan at least annually. The CORF must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

* * * * *

■ 45. Section 485.625 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 485.625 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The CAH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.

(2) *Testing.* The CAH must conduct exercises to test the emergency plan at least twice per year. The CAH must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise once per year. If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least annually, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

* * * * *

§ 485.627 [Amended]

■ 46. Section 485.627 is amended by removing and reserving paragraph (b)(1).

■ 47. Section 485.635 is amended by revising paragraph (a)(4) to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section and updated as necessary by the CAH.

* * * * *

■ 48. Section 485.645 is amended by—
■ a. Revising paragraph (d)(1);
■ b. Removing paragraph (d)(4);
■ c. Redesignating paragraphs (d)(5) through (9) as paragraphs (d)(4) through (8), respectively; and
■ d. Revising newly redesignated paragraphs (d)(4) and (7).

The revisions read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds").

* * * * *

(d) * * *

(1) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (g)(8) and (17), (g)(18) introductory text, and (h) of this chapter).

* * * * *

(4) Social services (§ 483.40(d) of this chapter).

* * * * *

(7) Dental services (§ 483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

* * * * *

■ 49. Section 485.727 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(5), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);
■ b. Adding paragraph (d)(1)(v); and
■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 485.727 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(5) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

* * * * *

(b) *Policies and procedures.* The Organizations must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and

updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The Organizations must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The Organizations must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the Organizations must conduct training on the updated policies and procedures.

(2) *Testing.* The Organizations must conduct exercises to test the emergency plan at least annually. The Organizations must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, the organization is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

* * * * *

■ 50. Section 485.914 is amended by revising paragraphs (d)(1) and (3) to read as follows:

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

* * * * *

(d) * * *

(1) The CMHC must update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred and in accordance with current standards of practice.

* * * * *

(3) For clients that receive PHP services, the assessment must be updated no less frequently than every 30 days.

* * * * *

■ 51. Section 485.920 is amended by revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, and (d) to read as follows:

§ 485.920 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The CMHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The CMHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The CMHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. If the emergency preparedness policies and procedures are significantly updated, the CMHC must conduct training on the updated policies and procedures.

(1) *Training.* The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least every 2 years.

(2) *Testing.* The CMHC must conduct exercises to test the emergency plan at least annually. The CMHC must:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based every 2 years. If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CMHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 52. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

■ 53. Section 486.104 is amended by revising paragraph (a) to read as follows:

§ 486.104 Condition for coverage: Qualifications, orientation and health of technical personnel.

* * * * *

(a) *Standard: qualifications of technologists.* All operators of the portable X-ray equipment meet the requirements of paragraph (a)(1) or (2) of this section.

(1) Successful completion of a program of formal training in X-ray technology at which the operator received appropriate training and demonstrated competence in the use of equipment and administration of portable x-ray procedures; or

(2) Successful completion of 24 full months of training and experience under the direct supervision of a physician who is certified in radiology or who possesses qualifications which are equivalent to those required for such certification.

* * * * *

■ 54. Section 486.106 is amended by revising paragraph (a)(2) to read as follows:

§ 486.106 Conditions for coverage: Referral for service and preservation of records.

* * * * *

(a) * * *

(2) Such physician or nonphysician practitioner's order meets the requirements at § 410.32 of this chapter, and includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

* * * * *

■ 55. Section 486.360 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2)(i).

The revisions and addition read as follows:

§ 486.360 Condition for coverage: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The OPO must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and, the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The OPO must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The OPO must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the OPO must conduct training on the updated policies and procedures.

(2) * * *

(i) Conduct a paper-based, tabletop exercise or workshop at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt from engaging in its next required testing exercise following the onset of the actual event.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 56. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C 1302, 1320a–7j, 1395aa, 1395bb, 1395hh and 1395ll).

§ 488.30 [Amended]

■ 57. Section 488.30(a) is amended in the definition for ''Provider of services, provider, or supplier'' by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs''.

■ 58. Section 488.61 is amended—

■ a. By revising the section heading;

■ b. In the introductory text by removing the phrase ''transplant centers'' and adding in its place the phrase ''transplant programs'';

■ c. In paragraph (a) by removing the phrases ''centers'' and ''center'' each time they appear and adding in their place the phrases ''programs'' and ''program,'' respectively;

■ d. In paragraph (a)(2) by removing the phrases ''Scientific Registry of Transplant Beneficiary (SRTR) center-specific'' and ''Scientific Registry of Transplant Recipient (SRTR) program-specific'' and adding in its place the phrase ''Scientific Registry of Transplant Recipient (SRTR) program-specific'';

■ e. By revising paragraph (a)(5);

■ f. By removing paragraph (c);

■ g. By redesignating paragraphs (d) through (h) as paragraphs (c) through (g), respectively;

■ h. By revising newly redesignated paragraphs (c), (d), (e) introductory text, (e)(1) introductory text, (e)(1)(iv), (e)(3), and (f)(1)(i), (ii), and (iii).

The revisions read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant programs.

* * * * *

(a) * * *

(5) If CMS determines that a transplant program has met the data submission, clinical experience, and outcome requirements, CMS will review the program's compliance with the conditions of participation contained at §§ 482.72 through 482.76 and §§ 482.90 through 482.104 of this chapter using the procedures described in subpart A of this part. If the transplant program is found to be in compliance with all the conditions of participation at §§ 482.72 through 482.104 of this chapter, CMS will notify the transplant program in writing of the effective date of its Medicare-approval. CMS will notify the transplant program in writing if it is not Medicare-approved.

* * * * *

(c) *Loss of Medicare approval.* Programs that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A program that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in paragraph (a) of this section;

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the program as a result of the loss of its Medicare approval status.

(d) *Transplant program inactivity.* A transplant program may remain inactive and retain its Medicare approval for a period not to exceed 12 months. A transplant program must notify CMS upon its voluntary inactivation as required by § 482.74(a)(3) of this chapter.

(e) *Consideration of mitigating factors in initial approval survey, certification, and enforcement actions for transplant programs*—(1) *Factors.* Except for situations of immediate jeopardy or deficiencies other than failure to meet requirements at § 482.80 of this chapter, CMS will consider such mitigating factors as may be appropriate in light of the nature of the deficiency and circumstances, including (but not limited to) the following, in making a decision of initial approval of a transplant program that does not meet the data submission, clinical experience, or outcome requirements:

* * * * *

(iv) Program improvements that substantially address root causes of graft failures or patient deaths, that have been implemented and institutionalized on a sustainable basis, and that are supported by outcomes more recent than the latest available SRTR report, for which there is a sufficient post-transplant patient and graft survival period and a sufficient number of transplants such that CMS finds that the program demonstrates present-day compliance with the requirements at § 482.80(c)(2)(ii)(C) of this chapter;

* * * * *

(3) *Timing.* Within 14 calendar days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval, and receive all information for consideration of mitigating factors within 120 calendar days of the CMS written notification for a deficiency due to data submission, clinical experience or outcomes at § 482.80 of this chapter. Failure to meet these timeframes may be the basis for denial of mitigating factors. CMS may permit an extension of the timeline for good cause, such as a declared public health emergency.

(f) * * *

(1) * * *

(i) Approve initial approval of a program's Medicare participation based upon approval of mitigating factors.

(ii) Deny the program's request for Medicare approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (g) of this section, when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (g) of this section.

* * * * *

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 59. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 60. Section 491.9 is amended by revising paragraph (b)(4) to read as follows:

§ 491.9 Provision of services.

* * * * *

(b) * * *

(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the RHC or FQHC.

* * * * *

■ 61. Section 491.11 is amended by revising paragraph (a) to read as follows:

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program.

* * * * *

■ 62. Section 491.12 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(v); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 491.12 Emergency preparedness.

* * * * *

(a) *Emergency plan.* The RHC or FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The RHC or FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The RHC or FQHC must develop and maintain an emergency preparedness communication plan that complies with

Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training and testing.* The RHC or FQHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(v) If the emergency preparedness policies and procedures are significantly updated, the RHC/FQHC must conduct training on the updated policies and procedures.

(2) *Testing.* The RHC or FQHC must conduct exercises to test the emergency plan at least annually. The RHC or FQHC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based functional exercise every 2 years. If the RHC or FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC or FQHC is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the RHC or FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC or FQHC's emergency plan, as needed.

* * * * *

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 63. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. l302 and l395hh).

■ 64. Section 494.62 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii);

■ b. Adding paragraph (d)(1)(vii); and

■ c. Revising paragraph (d)(2).

The revisions and addition read as follows:

§ 494.62 Condition of participation: Emergency preparedness.

* * * * *

(a) *Emergency plan.* The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least every 2 years. The plan must do all of the following:

* * * * *

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) *Policies and procedures.* The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

* * * * *

(c) *Communication plan.* The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

* * * * *

(d) *Training, testing, and orientation.* The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing, and patient orientation program must be evaluated and updated at least every 2 years.

(1) * * *

(ii) Provide emergency preparedness training at least every 2 years.

* * * * *

(vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures.

(2) *Testing.* The dialysis facility must conduct exercises to test the emergency plan at least annually. The dialysis facility must do all of the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, a facility-based functional exercise every 2 years. If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the actual event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

* * * * *

Dated: August 6, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 9, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–19599 Filed 9–17–18; 11:15 am]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 83 Thursday,
No. 183 September 20, 2018

Part III

Department of Transportation

Federal Motor Carrier Safety Administration

49 CFR Part 390
Lease and Interchange of Vehicles; Motor Carriers of Passengers; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 390

[Docket No. FMCSA–2012–0103]

RIN 2126–AC07

Lease and Interchange of Vehicles; Motor Carriers of Passengers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: FMCSA proposes to amend its May 27, 2015, *Lease and Interchange of Vehicles; Motor Carriers of Passengers* final rule in response to petitions for rulemaking and extend the January 1, 2019, compliance date to January 1, 2021. Today's proposal would narrow the applicability of the rule, by excluding from the definition of lease and the associated regulatory requirements, certain contracts and other agreements between motor carriers of passengers that have active passenger carrier operating authority registrations with FMCSA. For passenger carriers that would remain subject to the leasing and interchange requirements, FMCSA proposes to return the bus marking requirement to its July 1, 2015, state with slight modifications to add references to leased vehicles; revise the delayed writing of a lease during certain emergencies; and remove the 24-hour lease notification requirement. This proposal would be a deregulatory action as defined by Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs.''

DATES: Comments must be received by November 19, 2018.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2012–0103 using any of the following methods:

- *Website: http://www.regulations.gov.* Follow the instructions for submitting comments on the Federal electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Services, U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Ground Floor, Room W12–140, DOT Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Bitner, (202) 366–2400, *loretta.bitner@dot.gov,* Office of Enforcement and Compliance. FMCSA office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking (NPRM) is organized as follows:

I. Public Participation and Request for Comments

FMCSA encourages you to participate in this rulemaking by submitting comments, reply comments, and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you provide.

A. Submitting Comments

If you submit a comment, please include the docket number for this NPRM (Docket No. FMCSA–2012–0103), indicate the specific section of this document to which each comment applies, and provide a reason for each recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that the Agency can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2012–0103, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble

as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2012–0103, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

D. Waiver of Advance Notice of Proposed Rulemaking

Under 49 U.S.C. 31136(g)(1), as amended by section 5202 of the Fixing America's Surface Transportation (FAST) Act, Public Law 114–94, for any regulatory proposal likely to lead to the publication of a major rule,. FMCSA is required to publish an advance notice of proposed rulemaking (ANPRM), unless the Agency finds good cause pursuant to sec. 31136(g)(3) that an ANPRM is impracticable, unnecessary, or contrary to the public interest. For purposes of compliance with the FAST Act, the Agency has adopted the Congressional Review Act's definition of ''major rule'' (5 U.S.C. 804(2)), namely a rule that has an annual effect on the economy of $100 million or more. This final rule is not a major rule by that standard and 49 U.S.C. 31136(g)(1) therefore does not apply. Even if it were a major rule, however, FMCSA would find an ANPRM to be unnecessary.

On August 31, 2016, FMCSA published a notice of intent (2016 NOI) announcing that four potential changes to the final rule were under consideration and its plan to issue a rulemaking notice to reconsider those four areas of concern (81 FR 59951). The four changes are discussed in more detail later in this proposal.

FMCSA held a public roundtable on October 31, 2016 to discuss the four issues outlined in the 2016 NOI. The stakeholders represented spoke about those issues and provided information on how to address them. All public comments were placed in the docket of this rulemaking.

On June 16, 2017, FMCSA published a proposal (2017 proposal) in the **Federal Register** (82 FR 27768). The 2017 proposal provided information about FMCSA's planned revisions to the 2015 final rule and requested public comment on the proposed revisions. The 2017 proposal and comments received are discussed in more detail below.

The Agency's intent to issue this NPRM has been announced repeatedly, with opportunities for stakeholder comment available at each stage. Therefore, FMCSA believes a further opportunity to provide comments before issuance of this NPRM would be unnecessary.

E. Comments on the Collection of Information

If you have comments on the collection of information discussed in this NPRM, you must also send those comments to the Office of Information and Regulatory Affairs at Office of Management and Budget (OMB). To ensure that your comments are received on time, the preferred methods of submission are by email to *oira_submissions@omb.eop.gov* (include docket number ''FMCSA–2012–0103'' and ''Attention: Desk Officer for FMCSA, DOT'' in the subject line of the email) or fax at 202 395 6566. An alternative, though slower, method is by U.S. Mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, ATTN: Desk Officer, FMCSA, DOT.

II. Acronyms and Abbreviations

1935 Act	Motor Carrier Act of 1935.
1984 Act	Motor Carrier Safety Act of 1984.
ABA	American Bus Association.
BLS	Bureau of Labor Statistics.
CMV	Commercial Motor Vehicle.
DOT	United States Department of Transportation.
E.O	Executive Order.
FMCSA	Federal Motor Carrier Safety Administration.
FMCSRs	Federal Motor Carrier Safety Regulations, 49 CFR parts 350 through 399.
FR	Federal Register.
L&I	Licensing and Insurance.
MAP–21	Moving Ahead for Progress in the 21st Century Act.
MCMIS	Motor Carrier Management Information System.
NOI	Notice of Intent.
NPRM	Notice of Proposed Rulemaking.
NTSB	National Transportation Safety Board.
OMB	Office of Management and Budget.
PRA	Paperwork Reduction Act of 1995.
RFA	Regulatory Flexibility Act.
SBA	Small Business Administration.
SOC	Standard Occupational Classification.
STB	Surface Transportation Board.
UMA	United Motorcoach Association.
VIN	Vehicle Identification Number.

III. Executive Summary

A. Purpose of the Proposed Rule

Based on a review of the petitions for reconsideration and stakeholder input, FMCSA proposes to revise its regulations governing the lease and interchange of passenger-carrying commercial motor vehicles (CMVs). This proposed rule would exclude motor carriers that operate CMVs and have active operating authority registration with FMCSA to transport passengers—hereafter called ''authorized carriers'' or ''carriers with operating authority'' for the sake of simplicity—from the lease and interchange requirements. For leases between authorized carriers, because FMCSA believes their identity can be determined by other means, the assignment of responsibility for regulatory compliance would require no additional regulatory obligations.

FMCSA also proposes to extend the compliance date for the 2015 final rule to January 1, 2021, to give the Agency sufficient time to complete this rulemaking.

B. Summary of the Major Provisions

The proposed rule would (1) revise the definition of *lease* to exclude authorized carriers that grant the use of their vehicles to each other; (2) retain the provisions adopted in 2015 to identify the party responsible for compliance with the Federal Motor Carrier Safety Regulations (FMCSRs) when at least one of the passenger carriers involved in the lease or interchange of CMVs is not an authorized carrier; (3) ensure that a lessor subject to the proposed rule, *i.e.,* the entity providing the vehicle, surrenders control of the CMV for the full term of the lease or temporary exchange of CMVs; (4) remove the May 27, 2015 final rule's marking requirements and return the marking rule in 49 CFR 390.21(e), with slight modifications; (5) revise the provision allowing a delay in the completion of a lease during certain emergencies; and (6) remove the requirement that motor carriers that are hired to provide charter transportation and lease a CMV from another carrier notify the tour operator or group of passengers about the lease and the lessor. FMCSA requests comments to identify other methods to achieve the safety objectives of this rulemaking.

C. Costs and Benefits

The Agency estimates that annually 8,215 motor carriers of passengers and

537,134 passenger-carrying CMV trips would experience regulatory relief under the proposed rule. The Agency estimates that approximately 75 percent of these passenger carriers and CMV trips would experience full regulatory relief and would no longer be subject to the lease and interchange requirements of the 2015 final rule. The remaining 25 percent of these passenger carriers and CMV trips would experience partial regulatory relief and remain subject to reduced lease and interchange requirements, compared to those of the 2015 final rule.

As presented in Table 1, the Agency estimates that the proposed rule would result in a cost savings of $75.1 million on an undiscounted basis, $66.5 million discounted at 3 percent, and $57.5 million discounted at 7 percent over the 10-year analysis period. Expressed on an annualized basis, this equates to a 10-year cost savings of $7.8 million at a 3 percent discount rate and $8.2 million at a 7 percent discount rate.

TABLE 1—SUMMARY OF THE TOTAL COST OF THE PROPOSED RULE

[In thousands of 2016$]

Year	Passenger carriers experiencing regulatory relief under the proposed rule	Passenger-carrying CMV trips experiencing regulatory relief under the proposed rule	Undiscounted			Discounted	
			Lease and interchange costs [b]	Charter party notification costs	Total costs [a]	Discounted at 3%	Discounted at 7%
2019	7,906	516,952	($25,298)	($1,168)	($26,467)	($25,697)	($24,736)
2020	7,973	521,337	(4,042)	(1,178)	(5,221)	(4,921)	(4,560)
2021	8,041	525,758	(4,077)	(1,188)	(5,265)	(4,819)	(4,298)
2022	8,109	530,217	(4,111)	(1,198)	(5,310)	(4,718)	(4,051)
2023	8,178	534,714	(4,146)	(1,208)	(5,355)	(4,619)	(3,818)
2024	8,247	539,249	(4,182)	(1,219)	(5,401)	(4,523)	(3,599)
2025	8,317	543,822	(4,217)	(1,229)	(5,446)	(4,428)	(3,392)
2026	8,387	548,434	(4,252)	(1,239)	(5,493)	(4,336)	(3,197)
2027	8,459	553,085	(4,289)	(1,250)	(5,539)	(4,245)	(3,013)
2028	8,530	557,776	(4,326)	(1,261)	(5,586)	(4,157)	(2,840)
Total			(62,946)	(12,139)	(75,084)	(66,463)	(57,504)
Annualized					(7,508)	(7,792)	(8,187)

Notes:
[a] Total cost values may not equal the sum of the components due to rounding. (The totals shown in this column are the rounded sum of unrounded components.)
[b] Values shown in parentheses are negative values (*i.e.,* less than zero) and represent a decrease in cost or a cost savings.

The regulatory evaluation for the 2015 final rule addressed the potential safety benefits of lease and interchange requirements for motor carriers of passengers.[1] There were insufficient data and empirical evidence to demonstrate a measurable quantitative relationship between lease and interchange requirements for passenger-carrying CMVs and improved safety outcomes such as reduced frequency and/or severity of crashes or reduced frequency of violations. Therefore, FMCSA performed a threshold analysis, also referred to as a break-even analysis, estimating the reduction in crashes that would need to occur as a consequence of the 2015 final rule in order for the benefits of the rule to exactly offset the estimated costs of the rule.

In considering the potential impact to safety benefits from today's proposed rule, the Agency notes that there remains insufficient data and empirical evidence to clearly demonstrate a measurable quantitative relationship between lease and interchange requirements for passenger-carrying CMVs and improved safety outcomes. Lease and interchange requirements for motor carriers of passengers improve the ability of the Agency and our State partners to attribute the inspection, compliance, enforcement, and safety data to the correct motor carrier and driver, allowing FMCSA and our State partners to more accurately identify unsafe carriers and initiate appropriate interventions. FMCSA believes that the lease and interchange requirements of the proposed rule are a less costly and burdensome regulatory approach than the requirements of the 2015 final rule, yet still enable safety officials and the general public to sufficiently identify the passenger carrier responsible for safety. Therefore, the Agency does not anticipate any change to safety benefits as a result of the proposed rule.

IV. Legal Basis for the Rulemaking

This rule is based on the authority of the Motor Carrier Act of 1935 (1935 Act) and the Motor Carrier Safety Act of 1984 (1984 Act), as amended.

The 1935 Act authorizes DOT to ''prescribe requirements for—(1) qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier; and (2) qualifications and maximum hours of service of employees of, and standards of equipment of, a motor private carrier, when needed to promote safety of operation'' (49 U.S.C. 31502(b)).[2]

The 1984 Act confers on DOT authority to regulate drivers, motor carriers, and vehicle equipment. ''At a minimum, the regulations shall ensure that—(1) commercial motor vehicles are maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on operators of commercial motor vehicles do not impair their ability to operate the vehicles safely; (3) the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely . . .; and (4) the operation of commercial motor vehicles does not have a deleterious effect on the physical condition of the operators'' (49 U.S.C. 31136(a)). Section 32911 of the Moving Ahead for Progress in the 21st Century Act (MAP–21) [Pub. L. 112–141, 126 Stat. 405, 818, July 6, 2012] enacted a fifth requirement, *i.e.,* to ensure that ''(5) an operator of a commercial motor vehicle is not coerced by a motor carrier, shipper, receiver, or transportation intermediary to operate a commercial motor vehicle in violation of a regulation promulgated under this

[1] U.S. Department of Transportation (DOT), Federal Motor Carrier Safety Administration (FMCSA). ''Final Rule, Lease and Interchange of Vehicles; Motor Carriers of Passengers. Regulatory Evaluation.'' (Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation). May 2015. Available at: *https://www.regulations.gov/contentStreamer?documentId=FMCSA-2012-0103-0022&attachmentNumber=1&contentType=pdf* (accessed March 9, 2018).

[2] See *https://www.gpo.gov/fdsys/pkg/USCODE-2015-title49/pdf/USCODE-2015-title49-subtitleVI-partB-chap315.pdf.*

section, or chapter 51 or chapter 313 of this title'' [49 U.S.C. 31136(a)(5)].[3]

The 1984 Act also includes more general authority to ''(8) prescribe recordkeeping . . . requirements; . . . and (10) perform other acts the Secretary considers appropriate'' (49 U.S.C. 31133(a)).[4]

This rule imposes legal and recordkeeping requirements consistent with the 1935 and 1984 Acts on certain for-hire and private passenger carriers that operate CMVs, to enable safety officials and the general public to identify the passenger carrier responsible for safety. Currently, passenger-carrying CMVs and drivers are frequently rented, loaned, leased, interchanged, assigned, and reassigned with few records and little formality, thus obscuring the operational safety responsibility of many industry participants. Because this rule has only indirect and minimal application to drivers of passenger-carrying CMVs—at most, their employers might require them to pick up a lease document and place it on the vehicle, though that task could also be assigned to other employees—FMCSA believes that coercion of drivers to violate the rule will not occur.

Before prescribing any regulations, FMCSA must also consider their ''costs and benefits'' (49 U.S.C. 31136(c)(2)(A) and 31502(d)). Those factors are also discussed in this proposed rule.

V. Rulemaking History and Purpose

On September 20, 2013, FMCSA published an NPRM that discussed the National Transportation Safety Board's (NTSB) recommendation that FMCSA regulate the leasing of passenger carriers in much the same way as it regulates the leasing of for-hire property carriers (78 FR 57822). This NTSB recommendation resulted from several investigations of bus crashes that occurred in 2008 (78 FR 57822, 57824–57826). Starting in 2011, FMCSA investigated bus companies operating unsafely along the I–95 corridor. That investigation uncovered additional problems and serious safety violations with other carriers. As Agency investigators tried to understand the relationships and links between bus companies operating in complex networks, they encountered significant difficulties in identifying the motor carriers responsible for regulatory compliance on numerous trips. Vehicles and drivers were found to be frequently rented, loaned, leased, interchanged, assigned, and reassigned with few records and little formality, which obscured the operational safety responsibility of many industry participants. Multiple affiliated entities shared drivers and vehicles within their network intentionally to avoid identification of the motor carrier responsible for safety management, and to conceal excessive and illegal driver work hours that resulted in fatigue-related crashes in some cases.

Investigators were eventually able to document multiple patterns of serious safety violations by three networks of businesses that deliberately structured their operations to evade Federal regulatory oversight. Each time FMCSA had shut them down in the past, the three networks re-created or reincarnated themselves. These companies, which together transported almost 2,000 passengers daily, showed flagrant disregard for public safety by using drivers without valid commercial driver's licenses or medical qualification certificates, failing to conduct required drug testing of drivers, allowing or requiring drivers to exceed the maximum number of driving hours, and operating buses that were mechanically unsafe and in disrepair. FMCSA shut down these three networks of bus operators after a time-consuming, complex and detailed review of their operations.

In response to an NPRM intended to better ensure the correct identity of the motor carrier responsible for the operation of a passenger-carrying vehicle, 12 parties submitted comments. On May 27, 2015, FMCSA published a final rule (2015 final rule) concerning the lease and interchange of passenger-carrying CMVs (80 FR 30164). Although several of the proposed regulations were revised in response to comments received in response to the NPRM, the motorcoach industry took exception to some of the requirements of the final rule. The Agency published several documents to respond to the industry objections. These documents are discussed in detail in the following section.

VI. Petitions for Reconsideration and Subsequent Events

A. History of Petitions

The American Bus Association (ABA) and United Motorcoach Association (UMA) filed a joint request for an extension of the June 26, 2015, deadline for the submission of petitions for reconsideration of the final rule. On July 1, 2015, FMCSA extended the deadline to August 25, 2015 (80 FR 37553).

The Agency ultimately received 37 petitions for reconsideration which have been filed in the public docket referenced above. In addition, 11 informal comments were received. Upon review of these requests, FMCSA concluded that some have merit. FMCSA, therefore, extended the compliance date of the final rule from January 1, 2017, to January 1, 2018, to allow the Agency time to complete its analysis and amend the rule where necessary (82 FR 13998, Mar. 16, 2016).

The petitioners argued and explained in more detail that FMCSA had taken a regulatory scheme from the trucking industry and applied it to the bus industry, which has a vastly different operating structure and liability regime. Moreover, the application of these truck regulations to the bus industry offered no additional protection to the public from illegal or unsafe bus operators.

Petitioners further stated that the final rule created an economic and regulatory burden for passenger carriers that already operate safely and have a high degree of compliance. By imposing lease requirements, some of the petitioners argued, the rule did not affect carriers that choose to violate the regulations, but instead burdened those who already operate safely and are in compliance. Another petitioner stated that, while it supported efforts to identify and address chameleon carriers or carriers that may try to operate under the cloak of another carrier, the final rule did not accomplish this goal and, in fact, provided a roadmap for irresponsible carriers to operate legally under the authority of another carrier.

One carrier stated that it had identified several instances where the final rule lacked sufficient clarity to enable it to comply, and that these issue areas affected all of its operations. The final rule also added administrative costs and reduced operational flexibility for charter and tour bus operations, which would, in the end, reduce connectivity and transportation options for the traveling public. Another carrier named two insurance companies that have restrictions in their policies that prohibit the use of non-owned equipment and non-employed drivers, which were major concerns of the NPRM and final rule.

On August 31, 2016, FMCSA published the 2016 NOI announcing that the following four potential changes to the final rule were under consideration:

(1) Exclusion of ''chartering'' from the definition of *lease* in 49 CFR 390.5. The 2015 rule merged the concepts of leasing with ''chartering'' (subcontracting or reassigning

[3] See *https://www.gpo.gov/fdsys/pkg/USCODE-2015-title49/pdf/USCODE-2015-title49-subtitleVI-partB-chap311-subchapIII-sec31136.pdf.*

[4] See *https://www.gpo.gov/fdsys/pkg/USCODE-2015-title49/pdf/USCODE-2015-title49-subtitleVI-partB-chap311-subchapIII-sec31133.pdf.*

contracts). Authorized carriers routinely subcontract or reassign contracts to other authorized carriers to handle demand surges, emergencies, or events that require more than the available capacity. Subcontractors or assignees with their own operating authority have traditionally assumed responsibility for their own vehicles and drivers. Under the 2015 rule, however, a passenger carrier that subcontracted or reassigned work to another carrier would be responsible for that second carrier's compliance with the regulations. Petitioners claimed that making a carrier responsible for the subcontractor's or assignees' vehicles, drivers, and liability would make most short-term subcontracts impossible.

(2) Amending the CMV requirements for the location of temporary markings for leased/interchanged vehicles (49 CFR 390.21(f), 390.303(f)). The petitioners argued that the frequent marking changes needed during leases or interchanges would be impractical and unnecessary because the information required is recorded on the driver's records of duty status for safety inspectors and safety investigators to review; carriers would have to depend completely on drivers to properly change vehicle markings dozens of times per day in remote locations; and it would be unlikely that a member of the public would understand the significance of the markings in the event that he or she focused on the temporary ''operated by'' markings rather than the permanent markings on the bus representing the vehicle owner or long-term lessee.

(3) Changing the requirement that carriers notify customers within 24 hours when they subcontract service to other carriers (49 CFR 390.305). Petitioners argued that a 24-hour deadline is impractical because if an emergency maintenance issue occurs, it may not be possible to notify the customer in a timely manner, particularly if the issue occurs on the weekend, when the customer's offices are closed, and the trip is scheduled to start before the customer's Monday opening time.

(4) Expanding the 48-hour delay in preparing a lease to include emergencies when passengers are not actually on board a bus (49 CFR 390.303(a)(2)). Sometimes events requiring a replacement vehicle might occur when there are no passengers on a vehicle, such as when Amtrak or airline service is suspended or disrupted and buses are needed to transport stranded passengers. A bus operator contracted to provide the emergency service might need to obtain additional drivers and vehicles from other carriers to meet the demand. There might be a last-minute maintenance or mechanical issue, or driver illness, that arises late in the evening or during the night (such as on a multi-day charter or tour trip), or just prior to picking up a group for a charter or scheduled service run.

In the 2016 NOI, FMCSA announced its plan to issue a rulemaking notice to reconsider the four areas of concern listed above. The Agency expressed its belief that it might be possible to adopt less burdensome regulatory alternatives that would not adversely impact safety. FMCSA also explicitly denied other requested revisions because they would either have impaired the purpose of the final rule or did not represent practical alternatives.

Public Roundtable

FMCSA held a public roundtable on October 31, 2016 to discuss the four issues outlined in the 2016 NOI. The stakeholders represented spoke about those issues and provided the Agency with information on how to address them. All public comments were placed in the docket of this rulemaking.

Second Extension of Compliance Date and the Proposal in Response to Petitions for Reconsideration

On June 16, 2017, FMCSA published a final rule (2017 final rule) and a 2017 proposal in the **Federal Register** (82 FR 27766, and 27768). The 2017 final rule extended the compliance date of the 2015 final rule from January 1, 2018, to January 1, 2019. The 2017 proposal provided information about FMCSA's planned revisions to the 2015 final rule and requested public comment on the proposed revisions.

B. Discussion of Comments and Responses to the June 16, 2017 Proposal in Response to Petitions for Reconsideration

FMCSA received 24 comments in response to the 2017 proposal regarding the petitions for reconsideration. Two submissions requested an extension of time to comment, one from Coach USA and another from Adirondack Trailways, Pine Hill Trailways and New York Trailways.

The following commenters (hereafter the ''industry commenters''), submitted responses to the June 2017 proposal that were largely the same, both in wording and in format. The industry commenters include: AC Coach Operations, Inc. dba Anderson Coach and Travel, Adirondack Trailways, Pine Hill Trailways and New York Trailways (Responding together), ABA, Beeline Charters and Tours, Burlington Trailways, California Bus Association, Capitol Bus Lines Inc., Connecticut Bus Association, FTI Coach Lines, Georgia Motorcoach Operators Association, Indian Trails, Inc., Minnesota Charter Bus Operator's Association, Onondaga Coach Corp., Pennsylvania Bus Association, Shuttle Express, Inc., and Trans-Bridge Lines.

FMCSA also received unique comments from Academy Bus LLC and Greyhound Lines, Inc.; Delainey Banks, an individual; Coach USA, a non-carrier entity that controls numerous motor carriers of passengers; Reston Limousine; National Interstate Insurance; and the UMA.

Request for an NPRM

Neither the 2016 NOI nor the 2017 proposal contained specific regulatory text. The 2016 NOI announced FMCSA's intent to revise the 2015 final rule in response to petitions. As indicated above, the 2016 NOI described four major changes that were under consideration for regulatory changes.

In the 2017 proposal, the Agency identified its intention to revise the regulations to address ''chartering'' and the 48 hour delay in preparing a lease.

Comments: Industry commenters, including Academy Bus LLC., Greyhound Lines, Inc., UMA, Coach USA, and DATTCO, Inc. asked FMCSA to publish a formal NPRM that included proposed regulatory text. Coach USA, among others, noted that the 2017 proposal limited its discussion to only two of the four issues addressed in the 2016 NOI; however, they believed that all four issues should be addressed in rulemaking.

FMCSA Response: After publication of the 2016 NOI, FMCSA decided to publish an NPRM to continue the process of revising subpart F of 49 CFR part 390. FMCSA proposes to maintain and expand the emergency 48-hour delay in preparing a lease. FMCSA proposes to remove the 2015 final rule's CMV marking requirements when a passenger-carrying CMV is leased or interchanged. Furthermore, FMCSA proposes changes that would reduce the number of required leases because authorized carriers would not be subject to this proposed rule when using vehicles or acquiring transportation services from other authorized carriers.

Lease and Interchange

The 2015 final rule merged the concepts of leasing and chartering (or subcontracting). Carriers routinely subcontract work to other registered carriers to handle demand surges, emergencies, or events that require more than their available capacity.

Subcontractors with their own operating authority have traditionally assumed responsibility for their own vehicles or drivers. Under the 2015 rule, however, a passenger carrier that subcontracted work to another carrier would be responsible for that second carrier's compliance with the regulations. In the 2015 final rule, FMCSA used the following definition for ''Lease'' in § 390.5: ''Lease, as used in § 390.21(f) and subpart F of this part, means a contract or arrangement in which a motor carrier grants the use of a passenger-carrying commercial motor vehicle to another motor carrier, with or without a driver, for a specified period for the transportation of passengers, in exchange for compensation. The term lease includes an interchange, as defined in this section, or other agreement granting the use of a passenger-carrying commercial motor vehicle for a specified period, with or without a driver, whether or not compensation for such use is specified or required.'' The 2016 NOI indicated that the Agency would address, through rulemaking, this concern relating to the 2015 final rule's merger of the leasing and chartering concepts. In the 2017 proposal, FMCSA said that it intended to revise subpart F of 49 CFR part 390 to exclude ''chartering'' from the leasing requirements of that rule.

Comments: UMA, Greyhound, Academy Bus LLC, and others stated that the 2015 final rule is overly burdensome to motor carriers.

According to Coach USA Inc. and other commenters, the rule broadens the term ''lease'' to capture charter and similar operations, thus placing unnecessary burdens on compliant motor coach operators, while doing little to target the safety concern associated with non-compliant carriers. Commenters believed FMCSA should exclude from the definition of ''Lease'' in § 390.5 all passenger-carrying motor carriers that have FMCSA operating authority. Specifically, they asked the Agency to modify the definition of ''Lease'' by clarifying that it does not include a ''contract, subcontract, sublease, rental or charter arrangement between two or more passenger-carrying motor carriers where all parties have operating authority.''

The Minnesota Charter Bus Operator's Association stated that the rule would prohibit the necessary collaboration among multiple operators to meet the needs of large events that occur in Minnesota. This commenter added that the nature of the business requires operators to assist one another in the event of a mechanical breakdown, so they have to act quickly to service and protect the traveling public without the burden of the lease and marking requirement. Capitol Bus Lines, Inc. reported that, as a result of its need to comply with the 2015 final rule requirements, it lost the ability to provide shuttle service for a large fireworks display, which cost the company business. UMA believed the rule needlessly harms passenger groups and carriers in need of immediate assistance. Greyhound wrote the rule would severely curtail, if not eliminate, its leasing of buses to meet peak period demand.

Industry commenters believed that the rule may exacerbate the problem of non-compliant carriers by creating safe havens and encouraging a switch from chartering to passenger broker operations that the Agency has no authority to regulate. UMA commented that the rule does not identify chameleon carriers, but instead provides a roadmap for carriers that may have compliance or operating authority issues. UMA thought the rule might compel special event organizers and community leaders to spend needless time engaging multiple carriers or to turn to brokers.

While many commenters, including National Interstate Insurance, supported the exclusion of ''chartering'' from the leasing requirements of the rule, as stated in the 2017 proposal, some commenters, including Greyhound Lines, Inc., UMA, and Reston Limousine, wanted the Agency to clarify this term. In their joint request for an extension of time Adirondack Trailways, Pine Hill Trailways, and New York Trailways noted that the proposal equates ''chartering'' to ''subcontracting'' in one section, but then excludes the term ''chartering'' from the entire rule. Reston Limousine suggested defining ''lease'' to exclude contracts, subcontracts, or charter arrangements between two or more passenger-carrying motor carriers with valid individual USDOT operating authority.

Coach USA commented that the administrative and paperwork burden associated with the full range of other regulatory obligations related to chartering/subcontracting arrangements would be prohibitive. Further, Coach USA did not believe that it would be possible for a primary contractor to obtain insurance for vehicles operated by subcontractor, as the final rule seems to require. Coach USA noted that it is not practicable for the primary carrier to ensure that the subcontracting carrier is in full compliance with many FMCSA regulations, particularly given that arrangements with secondary carriers must often be made at the last minute.

Industry commenters added that the Agency should clarify that the current definition of the term ''interchange'' in § 390.5, as used in § 390.21(f) and subpart F of part 390, does not include the act of providing a passenger-carrying CMV by one motor carrier of passengers to another. The industry commenters suggested edits to the definition of ''interchange'' that they believed would resolve the issue.

FMCSA Response: Under this NPRM, authorized carriers would not be subject to leasing requirements when they use vehicles or acquire transportation services from other authorized carriers. FMCSA believes this proposed regulatory change, as explained elsewhere in this NPRM, would resolve the objections and concerns of most commenters, without impacting safety.

Assignment of Responsibility

The 2015 final rule governing the lease and interchange of passenger-carrying CMVs holds the lessee carrier directly responsible for violations of the FMCSRs.

Comments: UMA consistently argued that FMCSA should not compel two or more carriers, all possessing the requisite Federal operating authority, to enter a lease they would not otherwise enter when engaging each other's services. UMA believed that forcing passenger-carriers into a lease would compel the assignment of inspection violations and crashes to the lessee. The commenter wrote that inspections and crashes should be attributed to the chartered, contracted, or subcontracted carrier that possesses the sole, direct responsibility for compliance and control of vehicle maintenance and driver qualifications and behavior. UMA wrote that the burden of the 2015 rule falls disproportionately on small-fleet passenger carriers and disadvantages them by creating untenable regulatory liability.

FMCSA Response: Because Federal operating authority and the practices of the insurance industry both assign responsibility to the operating motor carrier, FMCSA agrees that there is no need to reassign responsibility through this rulemaking. As mentioned above, authorized carriers would not be subject to this proposed rule when they use vehicles or acquire transportation services from other authorized carriers. FMCSA believes that this proposed regulatory change would resolve the objections and concerns of most commenters, without impacting safety.

Marking Requirements

The 2015 final rule added a new § 390.21(f) to cover the marking of leased and interchanged passenger-carrying CMVs, as defined in § 390.5 (80 FR 30178). Carriers operating such CMVs must meet certain standards for marking in § 390.21. They must also display a placard, sign, or other permanent or removable device on the right (curb) side of the passenger-carrying CMV on or near the front passenger door. The device must show the name and USDOT number of the carrier operating the vehicle, preceded by the words ''operated by,'' *e.g.,* ''Operated by ABC Motorcoach, Inc., USDOT 12345678.''

Comments: Industry commenters generally argued that the 2015 final rule imposes burdensome marking requirements that are impractical, and that there are less burdensome ways to address the Agency's concerns. In their joint request for extension of time, Adirondack Trailways, Pine Hill Trailways, and New York Trailways commented that ''temporary markings'' is a matter of particular importance to them. They argued that the current final rules for temporary markings are unreasonable. They wrote that compliance would be impractical or unsafe, and arguably impossible, due to the design and construction of modern motor coaches.

In its comments, Coach USA recommended that the Agency eliminate the requirement to change vehicle markings when vehicles are exchanged between commonly owned carriers. Coach USA wrote that changing markings on vehicles exchanged between commonly-owned Coach USA companies would be highly burdensome given the large number of such exchanges. Coach USA commented that magnetic marking placards and paper signs are not a practical option. Placing a sign on the inside of the bus could obstruct the driver's view and/or would not meet the legibility requirements due to window glare or window tinting.

Coach USA also argued that requiring vehicles interchanged between commonly-owned companies to be marked in accordance with § 390.21 is likely to cause more confusion among passengers than it resolves. It reported that most of the vehicle exchanges between Coach USA carriers occur between companies that have ''Megabus.com'' written across their vehicles in huge letters. From the public's perspective, these motorcoaches are operated by Megabus. Coach USA did not believe that individuals would understand the temporary markings required by § 390.21 and thought they would result in confusion.

Greyhound Lines Inc. urged FMCSA to exempt from the temporary marking or placarding requirements the operation of vehicles that are being leased or interchanged between carriers that have FMCSA operating authority.

FMCSA Response: FMCSA proposes to remove the 2015 final rule's CMV marking requirements when a passenger-carrying CMV subject to the proposed rule is leased or interchanged. The Agency believes this proposed regulatory change would resolve the objections and concerns of the commenters. Under this NPRM, a motor carrier operating a passenger-carrying CMV under a lease having a term of not more than 30 calendar days could mark the CMV with either (1) the name and USDOT identification number of the lessee, or (2) the name and USDOT identification number of the lessor if, in the latter case, a fully complete lease is carried on the leased CMV during the full term of the lease. These proposals would remove the cost of additional marking of the vehicles while maintaining all of the information necessary for enforcement officials to identify the carrier for regulatory compliance. FMCSA proposes to add paragraph (e)(2)(v) to allow a passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) to be excepted from paragraphs (e)(2)(iii) and (iv) regarding a lease document with required information being carried on the vehicle, provided the lessor and lessee comply with the requirements of the provision in § 390.403(a)(2).

Twenty-Four Hour Notice of Lease

If a motor carrier was originally hired to provide charter transportation of passengers and subsequently subcontracted this work to another motor carrier of passengers, the 2015 final rule required the original motor carrier to notify the tour operator or group of passengers within 24 hours after hiring the subcontractor and advising that the transportation would be provided by the subcontractor. The 2016 NOI said that FMCSA was reconsidering that requirement based on petitioners' arguments that the 24-hour deadline is impractical in an emergency.

Comments: Industry commenters asked that the 24-hour requirement for notification be clarified in a proposed rule. They also believed that excluding passenger carriers that have operating authority from the definition of ''lease'' in § 390.5 would mean the requirements of § 390.305 Notification, would not apply.

Academy Bus LLC noted that the 24-hour notice to customers was not addressed in the 2017 proposal and said the issue was still of concern. Academy Bus LLC added that the industry is required to be flexible and respond to the public demand on very short notice.

Coach USA believed that excluding chartering and subcontracting arrangements would also eliminate the requirement to notify customers of subcontracting arrangements. Coach USA, however, supported a notification requirement for carriers that had been prohibited from operating by FMCSA or a State and intended to lease, interchange or otherwise convey use of a vehicle to another carrier. In fact, Coach USA argued that these carriers must provide written notice to FMCSA before taking such an action.

FMCSA Response: FMCSA proposes to remove the lease notification requirement, and believes its removal at this time may alleviate unnecessary regulatory burdens that, based on available evidence, do not significantly aid travel groups in arranging trips or avoiding particular carriers. If this conclusion is inaccurate, please provide data or information in regard to this matter.

Expanding the 48-Hour Delay in Preparing a Lease

When passengers are on a CMV and an emergency occurs that requires a replacement vehicle from another motor carrier, § 390.303(a)(2) allows the two carriers to postpone writing a lease or other written agreement for up to 48 hours. The Agency believed the 48-hour window would provide ample time for the parties to document the transaction.

One of the issues listed in the 2016 NOI was that FMCSA would reconsider expanding applicability of the 48-hour delay provision for preparing a lease to include emergencies when passengers are not actually on board a bus (81 FR 59952, Aug. 31, 2016). FMCSA provided examples of events that might require a motor carrier to obtain a replacement vehicle immediately:

- Buses might be needed to transport stranded passengers in the event that Amtrak or airline service was suspended or disrupted. A bus operator contracted to provide emergency service might need to obtain additional drivers and vehicles without delay;
- Last minute maintenance or mechanical issues, or driver illness, might arise late in the evening or during the night (such as on a multi-day charter or tour trip), or just prior to picking up

a group for a charter or scheduled service run.

In the 2017 proposal, FMCSA explained that it intended to broaden the emergency 48-hour delay provision for preparing a lease authorized by 49 CFR 390.303(a)(2) and remove the requirement that passengers actually be on board a bus when the exception occurs.

Comments: In response to the 2017 proposal, industry commenters indicated that the expansion of the 48-hour exemption could be addressed by changing the definitions in § 390.5. First, it was recommended that operations conducted under revenue pooling arrangements or common ownership and control be excluded from the definition of ''interchange'' in § 390.5. Second, FMCSA was asked to exclude passenger motor carriers from the definition of ''lease'' in § 390.5 when all parties have operating authority. Academy Bus LLC was concerned about lease preparation issues, noting that ''Our industry, by its nature, is required to be flexible and respond to the public demand on very short notice.''

An individual believed that the 48-hour time period for preparing leases might be a good idea for the trucking industry, but that is not the case for passenger carriers. This commenter stated that at peak times ''every worker is stretched thin and there is a need to bring in more operators to provide the same services,'' otherwise customers may be left stranded. In these instances, it is ''an emergency to both the busing companies and the customers to bring in another operator to provide the necessary backup to complete the job in an efficient manner. To combat this situation, companies need to work together before, during and after leasing passenger vehicles.'' This commenter also recommended that accountability be placed directly on the subcontractor and its driver.

Coach USA wrote that the exception in 49 CFR 390.303(a)(2) would likely apply only in rare instances if FMCSA exempted chartering and subcontracting arrangements from the regulations. Coach USA supported extending the 48-hour delay to cases of emergencies where passengers are not yet on the bus. Because operators will likely not have time to mark vehicles in the event of an emergency that requires replacement of a vehicle on very short notice, Coach USA proposed eliminating the final sentence of § 390.303(a)(2), ''The lessee must also mark the vehicle in accordance with § 390.21(f) before operating it.''

FMCSA Response: FMCSA adopts the petitioners' recommendation to expand the regulatory exception that permits the delayed writing of a lease during certain emergencies (*e.g.,* a crash, the vehicle is disabled) including when no passengers are on the vehicle. Therefore, FMCSA proposes to move the exception in 49 CFR 390.303(a)(2) to 49 CFR 390.403(a)(2). If a motor carrier obtains a replacement vehicle from, or subcontracts for service with, another motor carrier, the motor carriers may delay writing of a lease during these emergency situations. However, a summary document signed and dated by the lessee's driver or available company official must state: ''[Carrier A, USDOT number, telephone number] has leased this vehicle to [Carrier B, USDOT number, telephone number] pursuant to 49 CFR 390.403(a)(2)'' and the summary document must be carried on the replacement vehicle for the duration of the lease. Enforcement officials will be able to use this summary document to determine the identity of the carrier responsible for regulatory compliance.

Summary Document Requirements in § 390.301(b)(2) and (3)

In § 390.301(b)(2), the 2015 rule allows passenger-carrying CMVs to be exchanged or interchanged without leases or receipts among commonly owned and controlled motor carriers, provided the driver carries and produces, upon demand of a Federal, State, or local law enforcement official, a summary document listing certain information [*see* 80 FR at 30179].

Section 390.301(b)(3) provides that passenger-carrying CMVs may be exchanged or interchanged without leases or receipts among motor carriers that are party to a revenue pooling agreement approved by the Surface Transportation Board (STB) provided that the driver carries and, upon demand of a Federal, State, or local law enforcement official, displays other information, including a summary document [*see* 80 FR at 30179].

Neither the 2016 NOI nor the 2017 proposal addressed the summary document requirements.

Comments: The industry commenters suggested removing the requirements in § 390.301(b)(2) and (3) and instead including language about an abbreviated summary document in the definition of ''interchange'' in § 390.5. If the interchange occurred among commonly owned/controlled motor carriers, the summary document would identify the carriers in that ''family,'' including USDOT numbers and business addresses. If the interchange occurred pursuant to a revenue pooling agreement approved by the STB, the summary document would identify the parties to the agreement, including the USDOT numbers and business addresses. These summary documents would be produced upon the demand of a law enforcement official.

In its request for an extension of time, Coach USA argued that the information required in § 390.301(b)(2)(i) is trip specific, and would require the company to create a new summary document for each of more than 10,000 trips annually. Such a document would impose an unnecessary regulatory burden. Coach USA requested that the summary document required by this provision include only a ''listing of all members of the corporate family along with their USDOT numbers, business addresses and contact telephone numbers.'' The company also asked the Agency to clarify that any summary document may be maintained in electronic format and stored on an electronic logging device.

In its response to the Agency's 2017, proposal, Coach USA, like other industry commenters, reiterated its previous comments.

FMCSA Response: Since this proposed rule would not apply to transactions between or among authorized carriers under the proposed exception in § 390.401(b)(1) *Contracts and agreements between motor carriers of passengers with active passenger carrier operating authority registrations,* FMCSA believes that regulatory exceptions for commonly owned and controlled carriers, and carriers participating in STB-approved revenue pooling agreements, are no longer necessary. The industry commenters suggested making the rule inapplicable to commonly owned and controlled carriers and carriers participating in STB-approved revenue pooling agreements, and the Agency agrees with these comments. Therefore, FMCSA proposes to rescind the exceptions in 49 CFR 390.303(b)(2) and (b)(3). All passenger carriers that are commonly owned and controlled or participate in STB-approved revenue pooling agreements operate in interstate commerce and have operating authority. An authorized carrier that obtains a vehicle from another commonly owned and controlled authorized carrier or another participant in an STB-approved pooling agreement, would not be subject to this proposed rule.

VII. General Discussion of the Proposed Rule

A. The Proposed Rule

FMCSA proposes removing and reserving subpart F of part 390, moving it to subpart G with the same title,

''Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles,'' and making some further regulatory changes discussed later in this document. FMCSA is planning to use subpart F in a future NPRM to be published under RIN 2126–AB56, Unified Registration System Enhancements and Updates.

Definitions

The Agency proposes to revise the definition of *lease* in § 390.5 to include only contracts and agreements in which a motor carrier grants the use of a passenger-carrying CMV to another motor carrier when at least one of the motor carriers is not an authorized carrier.[5] Authorized carriers routinely assist one another by providing transportation services during demand surges, emergencies, or events that require more than their available capacity. These common agreements, some of which amount to subcontracting, would not meet the regulatory definition of a *lease* in this proposed rule. Authorized carriers that are hired by another authorized carrier have traditionally assumed responsibility for their own regulatory compliance and liability. This practice has long been acceptable to the insurance industry. Furthermore, authorized carriers are readily identifiable to enforcement personnel, making a separate lease agreement assigning regulatory responsibility unnecessary.

The definition of *lease* would become narrower by including only contracts and agreements to grant the use of a passenger-carrying CMV between motor carriers when one (or more) such carrier does not have operating authority. The term *lease* would also be revised with added language to include circumstances when no compensation is specified. The terms *lessee* and *lessor* would both be revised slightly to specify that the granting of passenger-carrying CMV usage is through a *lease.*

Marking of Self-Propelled CMVs and Intermodal Equipment

Section 390.21 (suspended) and 390.21T would be returned nearly to the form before the March 27, 2015, final rule. FMCSA would remove the special marking regulations for leased and interchanged passenger-carrying CMVs in paragraph (f). Section 390.21 (suspended) and 390.21T would be revised to treat leased passenger-carrying CMVs like all other rented CMVs. For a lease of 30 calendar days or less, the lessee can opt to mark the vehicle with either the lessee's information or the lessor's information. However, the latter would require a fully executed copy of the lease be carried on the vehicle.

If the motor carrier is operating a passenger-carrying CMV under a lease or rental agreement for more than 30 calendar days, such CMV must be marked with the lessee's identification information. In a lease situation, the operating motor carrier is the lessee. These revised regulations would address petitioners' concerns that there is no easy way to display a temporary marking on certain passenger-carrying motor vehicles for short term leases. FMCSA specifically requests comments from State Agencies that participate in the Motor Carrier Safety Assistance Program about the effectiveness of these proposed marking regulations for leased passenger-carrying CMVs and any potential inspection or enforcement problems.

General Applicability and Exceptions

The general applicability section would be revised slightly to reflect the removal of exceptions in paragraph (b). Section 390.401(b) would be modified in several ways. First, a new exception would appear in paragraph (b)(1) to exclude from the rule contracts and agreements between passenger carriers with active operating authority when one such carrier acquires transportation services from another such carrier. Second, the current exception for financial leases in paragraph § 390.301(b)(1) would be moved to paragraph § 390.401(b)(2) as an exception with a revision. The provision that the financial organization, manufacturer, or dealer must not be a motor carrier to utilize the exception from the rule is proposed for removal because such entities are motor carriers when they move their vehicle inventory between business locations before purchases. Third, the limited exception in paragraph (b)(2) for passenger-carrying CMVs exchanged or interchanged between or among commonly owned and controlled motor carriers would be removed. Fourth, the limited exception in paragraph (b)(3) for passenger-carrying CMVs exchanged or interchanged between or among motor carriers that are a party to a revenue pooling agreement approved by the STB in accordance with 49 U.S.C 14302 would also be removed.

Lease and Interchange Requirements

Lease and interchange requirements would be revised by removing § 390.303(a)(1)(iii), which covers written agreements governing the renting, borrowing, loaning, or similar transfer of a passenger-carrying CMV from another party. The rule would be revised and moved to § 390.403(a)(1) to include such transactions as either a lease or interchange, which makes paragraph (a)(1)(iii) unnecessary. FMCSA is proposing to expand the emergency-related exception in § 390.303(a)(2) (after transferring it to § 390.403(a)(2)) that allows the postponement of the completion of a lease for up to 48 hours for situations, such as a crash or vehicle breakdown, when a replacement vehicle must be immediately obtained from another motor carrier. Industry commenters requested this expansion of the limited exception and FMCSA agrees with them. FMCSA proposes to allow the exception even when passengers are not on the bus.

Section 390.403(b) specifies the contents of lease and interchange documents. This paragraph requires the lease, interchange agreement, or other agreement to contain: (1) The name of the vehicle manufacturer, the year of manufacture, and the last 6 digits of the Vehicle Identification Number; (2) the legal names, contact information, and signatures[6] of both parties; (3) the time and date when the lease begins and ends; and (4) a statement that the lessee has exclusive possession and control of the leased vehicle and is responsible for regulatory compliance.

Current § 390.303(b)(4)(i)–(iii) is a slightly revised version of 49 CFR 376.12(c)(1), (2) and (4). Paragraph (b)(4)(i) is essential because it sets forth the basic reason for a lease, from FMCSA's point of view, to assign full responsibility for regulatory compliance to the lessee. FMCSA proposes to make this paragraph more concise. Current paragraph (b)(4)(ii) would be moved to § 390.403(b)(4)(ii) and would retain only the last sentence of that provision. Paragraph (b)(4)(iii) is a useful disclaimer, should the issue of status of the lessor (contractor or employee) arise in a tax context, but FMCSA does not believe it is essential. Therefore, FMCSA proposes to shorten paragraphs (b)(4)(i) and (b)(4)(ii) and remove paragraph (b)(4)(iii).

FMCSA proposes to remove the requirement in § 390.303(b)(5) that the lease contain a statement that the lessee is responsible for compliance with the

[5] This rulemaking does not propose a change to the definition of *lease* in the context of property-carrying vehicles in 49 CFR 376.2.

[6] FMCSA allows the use of electronic signatures in accordance with the Government Paperwork Elimination Act (Pub. L. 105–277, Title XVII, Secs. 1701–1710, 44 U.S.C. 3504 note, 112 Stat. 2681–749). See 76 FR 411, Jan. 4, 2011 and the Electronic Signature final rule's §§ 390.5, 390.5T, and 390.32, April 16, 2018 (83 FR 16226–7).

insurance requirements of 49 CFR part 387.

Section 390.303(c) and (d) would be merged and made more concise. Revised § 390.403(c) would state that a copy of the lease must be carried in the passenger-carrying CMV during the period of the lease or interchange agreement. Both the lessee and lessor would retain the lease or interchange agreement for 1 year afterwards.

Section 390.303(e) would be removed. FMCSA has decided it does not need receipts when vehicles are surrendered to the lessee and returned to the lessor. If FMCSA or another government enforcement agency sought to assign a safety incident to the lessee or the lessor based on a lease or other agreement that had already been terminated, the former parties to the lease would have to decide how to document that premature termination.

FMCSA proposes to remove the requirements in § 390.303(f) for additional temporary markings of leased and interchanged passenger-carrying CMVs, and to return to the text of the marking rule in § 390.21(e)[7] that was effective on July 1, 2015, with slight modifications. The modifications would add references to leased CMVs in paragraph (e) to provide a similar option to rented CMVs.

FMCSA believes that this eliminates one of petitioners' major objections to the 2015 final rule. The proposed rule would require a leased passenger-carrying CMV be marked with the lessee's identification information if the lease is longer than 30 days. Leased passenger-carrying CMVs would be required to be marked with either the lessor's or lessee's identification information if the lease is 30 days or less.

Finally, the proposed rule removes the requirement in § 390.305 to notify the passenger group or their representative within 24 hours after the primary contractor reassigns the transportation to a subcontractor.

B. Examples of Proposed Rule Implementation

The following examples illustrate the proposed application of this rulemaking:

Complete Contract Transfer Example

Authorized carrier A is contracted to transport a tour or travel group on a trip, but finds itself without the capacity to accommodate the group. Carrier A completely transfers the contract to authorized carrier B that has the necessary capacity. Carrier A may or may not pay a fee to carrier B for taking over the contract. A complete transfer would require carrier A to cancel its contract with the customer and carrier B to create a new contract with the customer. The proposed rule would not apply to these transactions because these transactions do not qualify as a ''lease'' (or interchange), as defined in § 390.5, of a passenger-carrying CMV.

Complete Subcontracting Among Authorized Carriers

Authorized carrier A lacks the capacity to execute a contracted trip and hires authorized carrier B to make the trip while maintaining its contract with the customer. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the trip. This arrangement is not a lease, first because carrier B is not granting the use of a passenger-carrying CMV to carrier A, and second because both carriers are authorized carriers. Instead, carrier B is making the trip in its own name, on its own authority, with its own vehicles and is therefore responsible for compliance with the FMCSRs. The proposed rule therefore would not apply to this arrangement.

Partial Subcontracting Among Authorized Carriers

Assuming the same facts as described above, except that authorized carrier A provides some of the transportation service while contracting with authorized carrier B for the remainder, this arrangement is not a lease, first because carrier B is not granting the use of a passenger-carrying CMV to carrier A, and second because both carriers are authorized carriers. Carrier A pays carrier B for the transportation service as part of a charter contract. Carrier B is not surrendering control of a passenger-carrying CMV to carrier A for its own use. Both carriers are authorized carriers providing transportation in their own name, on their own authority, with their own vehicles, and each is independently responsible for compliance with the FMCSRs.

Subcontracting Among Regular Route Authorized Carriers

Authorized carrier A, which provides regular route passenger transportation services according to a fixed schedule, finds itself without the capacity to execute a route. Carrier A hires authorized carrier B to continue this service. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the transportation service. This arrangement is not a lease, first because carrier B is not granting the use of a passenger-carrying CMV to carrier A, and second because both carriers are authorized carriers. This arrangement is also not an interchange because carriers A and B are not conducting a through movement. The proposed rule would not apply to this arrangement. Carrier B will conduct the transportation in its own name, on its own authority, with its own vehicle(s), and is therefore responsible for compliance with the FMCSRs.

Other Business Arrangements Between Passenger Carriers

Example 1

Carrier A is exempt under 49 U.S.C. 13506 from the requirement for operating authority—for example, because of the hotel exemption in section 13506(a)(3)[8]—but finds itself without the capacity to accommodate a group that it originally intended to transport. When this occurs, carrier A hires authorized carrier B to provide charter passenger transportation of the group in whole or in part. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the transportation service, but is not a lessee of carrier B's vehicle. Therefore, this arrangement is not a lease. Carrier B does not claim the exemption in section 13506(a)(3) but conducts the transportation in its own name, on its own authority, with its own vehicle(s) and is therefore responsible for compliance with the FMCSRs. The proposed rule would not apply to this arrangement.

Example 2

Private motor carrier of passengers A finds itself without the capacity to transport the members of its organization. Carrier A therefore hires authorized carrier B to provide charter passenger transportation of the group in whole or in part. This arrangement is documented by a charter contract between carriers A and B. Carrier A pays carrier B for the transportation service. Carrier A is not a lessee and the arrangement is not a lease or interchange because carrier B conducts the transportation in its own name, on its own authority, with its own vehicle(s) and is therefore responsible for compliance with the FMCSRs. The

[7] See e-CFR text in effect on July 1, 2015 at *https://www.ecfr.gov/cgi-bin/text-idx?SID=b9ddca68b462ed0f3d5758839de97752&pitd=20150701&node=pt49.5.390&rgn=div5#se49.5.390_121.*

[8] Section 13506 lists the miscellaneous motor carrier transportation exemptions. Under section 13506(a)(3), neither the Secretary nor the Board has jurisdiction over a motor vehicle owned or operated by or for hotel patrons between the hotel and the local station of a carrier.

proposed rule would not apply to this arrangement.

Example 3

Carrier A is an exempt for-hire motor carrier of passengers (under 49 U.S.C. 13506) that finds itself without the capacity to accommodate a group it originally intended to transport. Carrier A uses a passenger-carrying CMV owned by authorized carrier B. This transaction is a lease under the proposed rule and would be subject to its requirements because carrier A is not authorized to operate for-hire in interstate commerce. In this case, carrier B is a lessor that is surrendering control of a passenger-carrying CMVs to carrier A for the use of that carrier. Carrier A will conduct the transportation in its own name under its own safety registration (*i.e.,* USDOT number) with the CMV leased from carrier B, with or without drivers provided by carrier B, and is therefore responsible for compliance with the FMCSRs.

Example 4

Private motor carrier of passengers A finds itself without the capacity to accommodate a group it originally intended to transport. Carrier A uses a passenger-carrying CMV owned by authorized carrier B. This transaction is a lease under the proposed rule and would be subject to its requirements because carrier A is not authorized to operate for-hire in interstate commerce. In this case, carrier B is a lessor that is surrendering control of a passenger-carrying CMVs to carrier A for the use of that carrier. Carrier A will conduct the transportation in its own name under its own safety registration (*i.e.,* USDOT number) with the CMV leased from carrier B, with or without drivers provided by carrier B, and is therefore responsible for compliance with the applicable FMCSRs.

Example 5

Authorized carrier A lacks the capacity to execute a contracted trip and uses a passenger-carrying CMV owned by private motor carrier of passengers, carrier B. This transaction is a lease under the proposed rule and would be subject to its requirements because private carrier B is not authorized to operate for-hire in interstate commerce and cannot be hired to provide transportation. In this case, carrier B is a lessor that is surrendering control of its passenger-carrying CMV to carrier A. Carrier A will conduct the transportation in its own name, under its own authority, with the CMV leased from the private motor carrier of passengers, with or without drivers provided by carrier B, and is therefore responsible for compliance with the FMCSRs.

Example 6

Private motor carrier of passengers A finds itself without the capacity to transport the members of its organization and uses a passenger-carrying CMV owned by private motor carrier of passengers B. This transaction is a lease under the proposed rule and would be subject to the requirements of this rule because neither carrier has the authority to conduct for-hire operations in interstate commerce. In this case, carrier B is a lessor that is surrendering control of its passenger-carrying CMV to carrier A for the use of that carrier. Carrier A will conduct the transportation in its own name, under its own safety registration (*i.e.,* USDOT number), with the CMV leased from carrier B, with or without drivers provided by carrier B, and is therefore responsible for compliance with the applicable FMCSRs.

Example 7

For-hire passenger carrier A had its operating authority revoked for lack of adequate insurance coverage. Carrier A wishes to generate revenue from its otherwise idle CMVs. It therefore negotiates an arrangement with authorized carrier B to surrender control of its passenger-carrying CMVs to carrier B for a fee. This arrangement is a lease under the proposed rule and would be subject to its requirements because carrier A is not authorized to operate for-hire in interstate commerce. In this case, carrier A is simply a lessor. Carrier B would conduct the transportation in its own name, on its own authority, with the CMVs leased from carrier A, with or without drivers provided by carrier A, and is therefore responsible for compliance with the FMCSRs.

C. Alternatives

FMCSA requests comments to identify other methods to achieve the safety objectives of this rulemaking.

VIII. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, United States territories). Motor carriers and drivers are subject to the laws and regulations of the countries in which they operate, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences among nations.

IX. Section-by-Section Description of the Proposed Rule

A. Section 390.5 (Suspended) and 390.5T Definitions

Section 390.5 (suspended) and 390.5T would be amended to revise the definitions of *lease, lessee,* and *lessor* and all of these terms would apply specifically to motor carriers of passengers.

B. Section 390.21 (Suspended) and 390.21T Marking of Self-Propelled CMVs and Intermodal Equipment

Section 390.21 (suspended) and 390.21T would be returned nearly to the form before the March 27, 2015, final rule. In the paragraph (e) header, FMCSA replaces ''Rented property-carrying commercial motor vehicles'' with the header phrase ''*Rented CMVs and leased passenger-carrying CMVs.*'' Throughout paragraph (e), the Agency adds the phrase ''or lease'' after the term ''rental agreement.'' When referring to a ''renting motor carrier,'' the Agency adds the phrase ''or lessee'' immediately after it. In paragraph (e)(2)(iv), in addition to the cross reference to the property-carrying leasing regulations in 49 CFR part 376, FMCSA adds a cross reference to the passenger-carrying leasing regulations in subpart G of part 390 so that the revised sentence reads ''See the property-carrying leasing regulations at 49 CFR part 376 and the passenger-carrying leasing regulations at subpart G of this part for information that should be included in all leasing documents.'' FMCSA proposes to add paragraph (e)(2)(v) to allow the passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) to be excepted from paragraphs (iii) and (iv) regarding a lease document with required information being carried on the vehicle, provided the lessor and lessee comply with the requirements of the provision in § 390.403(a)(2).

In paragraph (f), FMCSA would remove the special marking regulations for leased and interchanged passenger-carrying CMVs. This proposal would redesignate paragraphs (g) and (h) as paragraphs (f) and (g), respectively, as they were on July 1, 2015.[9]

C. Part 390, Subpart F Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

Subpart F, including §§ 390.301, 390.303, and 390.305, would be removed and reserved.

[9] See *https://www.ecfr.gov/cgi-bin/text-idx?SID=b9ddca68b462ed0f3d5758839de97752&pitd=20150701&node=pt49.5.390&rgn=div5#se49.5.390_121.*

D. Part 390, Subpart G Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

Subpart G, consisting of §§ 390.401 and 390.403, would be added.

E. Section 390.401 Applicability

Paragraph (a) would add the general applicability for passenger-carrying CMV leases and interchanges as the terms ''lease'' and ''interchange'' would be defined in this proposal's §§ 390.5 (suspended) and 390.5T.

Paragraph (b) would provide the two proposed exceptions to the general rule. Paragraph (c) would provide that if the use of a passenger-carrying commercial motor vehicle is conferred between motor carriers subject to this proposal and either carrier fails to meet all applicable requirements of subpart G, both motor carriers shall be subject to a civil penalty.

F. Section 390.403 Lease and Interchange Requirements

In paragraph (a)(1), this proposal would set out the two instances in which a lease or other agreement is required (and the lease or agreement must then meet the conditions of paragraphs (b) and (c) of this section). In paragraph (a)(2), this proposal would allow the delayed writing of a lease after an emergency, such as a disabled vehicle, that disrupts or delays a trip, and would not limit the exception to times when passengers are on the bus.

Paragraph (b) would specify the four minimum required items of any lease, sublease, or interchange document required under this proposal: (1) *Vehicle identification information;* (2) *Parties;* (3) *Specific duration;* and (4) *Exclusive possession and responsibilities.*

Paragraph (c) would provide when a copy of the lease must be on the passenger-carrying CMV and how long both the lessor and lessee must retain copies of the lease, sublease, or agreement.

X. Regulatory Analyses

A. E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA performed an analysis of the impacts of the proposed rule and determined it is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, October 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, January 21, 2011), Improving Regulation and Regulatory Review. Accordingly, the Office of Management and Budget (OMB) has not reviewed it under that Order. It is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980; 44 FR 11034 (February 26, 1979)).

As described earlier, the proposed rule would reduce the scope of the lease and interchange requirements for motor carriers of passengers. Furthermore, those passenger carriers and passenger-carrying CMV trips for which the proposed rule would remain applicable would be subject to lease and interchange requirements that are reduced in comparison to those of the 2015 final rule. At the same time, FMCSA believes that the lease and interchange requirements of the proposed rule would still enable safety officials and the general public to sufficiently identify the passenger carrier responsible for safety. As a consequence, FMCSA estimates that the proposed rule would result in a cost savings, but would not result in any change to safety benefits.

The Agency estimates that the proposed rule would result in a cost savings of $75.1 million on an undiscounted basis, $66.5 million discounted at 3 percent, and $57.5 million discounted at 7 percent over the 10-year analysis period. Expressed on an annualized basis, this equates to a 10-year cost savings of $7.8 million at a 3 percent discount rate and $8.2 million at a 7 percent discount rate, again representing a decrease in cost or a cost savings.

Key Inputs to the Analysis

The proposed rule revises regulations established in the 2015 final rule, therefore the 2015 final rule serves as the baseline against which the effects of the proposed rule are evaluated. Many of the key inputs to this analysis of the proposed rule are based on the same data sources and methods as those developed and used in the evaluation of the 2015 final rule, with various updates made as needed to reflect more recently available data and information. Therefore, a copy of the regulatory evaluation for the 2015 final rule is available in the docket for the proposed rule, and, where applicable, the Agency cites that document in the analysis below.[10] A 10-year analysis period of 2019 to 2028 is utilized for this analysis of the proposed rule, and all monetary values are expressed in 2016 dollars.

Number of Passenger Carriers Experiencing Regulatory Relief Under the Proposed Rule

The Agency estimates that an annual average of 8,215 motor carriers of passengers would experience regulatory relief under the proposed rule, as discussed below. This represents the average over the 10-year analysis period of the individual annual estimates of the total number of passenger carriers experiencing regulatory relief under the proposed rule, which are presented in Table 2. As also shown in Table 2, the Agency estimates that approximately 75 percent of this total number of passenger carriers would experience full regulatory relief and would no longer be subject to the lease and interchange requirements for passenger-carrying CMVs as a consequence of the proposed rule. The remaining 25 percent of these passenger carriers would experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 final rule.

TABLE 2—ESTIMATED NUMBER OF PASSENGER CARRIERS EXPERIENCING REGULATORY RELIEF UNDER THE PROPOSED RULE

Year	Passenger carriers experiencing full regulatory relief under the proposed rule	Passenger carriers experiencing partial regulatory relief under the proposed rule	Total passenger carriers experiencing regulatory relief under the proposed rule
2019	5,929	1,977	7,906
2020	5,980	1,993	7,973

[10] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.''

TABLE 2—ESTIMATED NUMBER OF PASSENGER CARRIERS EXPERIENCING REGULATORY RELIEF—Continued UNDER THE PROPOSED RULE

Year	Passenger carriers experiencing full regulatory relief under the proposed rule	Passenger carriers experiencing partial regulatory relief under the proposed rule	Total passenger carriers experiencing regulatory relief under the proposed rule
2021	6,031	2,010	8,041
2022	6,082	2,027	8,109
2023	6,134	2,044	8,178
2024	6,185	2,062	8,247
2025	6,238	2,079	8,317
2026	6,290	2,097	8,387
2027	6,344	2,115	8,459
2028	6,397	2,133	8,530
Annual average	6,161	2,054	8,215

To derive the estimates presented in Table 2 of the number of passenger carriers experiencing regulatory relief under the proposed rule, FMCSA first estimated the number of passenger carriers that, in the absence of the proposed rule, would be affected by the lease and interchange requirements of the 2015 final rule. This estimate is based on the same data sources and methods as those developed and used in the evaluation of the 2015 final rule [11] but updated to reflect more recently available data and information. Data from the FMCSA Motor Carrier Management Information System (MCMIS) and the FMCSA Licensing and Insurance (L&I) system were used to develop a new baseline value for the reported number of all active interstate passenger carriers operating in the U.S. as of the end of calendar year 2017, namely 13,386 carriers.[12] [13]

Of this total population, the Agency estimates that, in the absence of the proposed rule, 7,774 of these passenger carriers would be subject to the May 2015 final rule. This estimate is based on the same methods as those developed and used in the evaluation of the 2015 final rule, and assumes that under that rule 100 percent of authorized for-hire carriers, 100 percent of exempt for-hire carriers, and 10 percent of private passenger carriers would be subject to the lease and interchange requirements for passenger-carrying CMVs.[14]

TABLE 3—REPORTED NUMBER OF ACTIVE INTERSTATE PASSENGER CARRIERS OPERATING IN THE U.S. (AS OF DECEMBER 29, 2017), AND ESTIMATED NUMBER THAT WOULD BE SUBJECT TO THE MAY 2015 FINAL RULE IN THE ABSENCE OF THE PROPOSED RULE

Type of passenger carrier operation	Total number of carriers	Number (and percent) estimated to be subject to the May 2015 final rule in the absence of the proposed rule
Authorized For-Hire [(a)]	6,629	6,629 (100% of total).
Exempt For-Hire (9+) [(b)]	340	340 (100% of total).
Exempt For-Hire (16+) [(c)]	181	181 (100% of total).
Private (business) [(d)]	2,599	260 (10% of total).
Private (non-business) [(e)]	3,637	364 (10% of total).
Total [(f)]	13,386	7,774.

Notes:

(a) A commercial entity whose primary business activity is the transportation of passengers by motor vehicle for compensation.

(b) A for-hire entity that is exempt under 49 U.S.C. 13506, and operates at least one passenger vehicle designed or used to accommodate 9 or more passengers including the driver.

(c) A for-hire entity that is exempt under 49 U.S.C. 13506, and operates at least one passenger vehicle designed or used to accommodate 16 or more passengers including the driver.

(d) A private entity engaged in the interstate transportation of passengers which is provided in the furtherance of a commercial enterprise and is not available to the public at large.

(e) A private entity involved in the interstate transportation of passengers that does not otherwise meet the definition of a ''private (business)'' motor carrier of passengers as noted above.

[11] Further details regarding the specific data sources and methods can be found in DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Pages 9–12.

[12] U.S. Department of Transportation (DOT), Federal Motor Carrier Safety Administration (FMCSA). Motor Carrier Management Information System (MCMIS), and Licensing and Insurance (L&I) system. Snapshots as of December 29, 2017 (DART request ID #38883).

[13] The total number of 13,386 passenger carriers as of the end of 2017 actually represents 11,705 unique carriers, because some carriers provide passenger service in more than one of the operation classifications shown. Consistent with the approach used in the regulatory evaluation for the May 2015 final rule, the larger number was used here so as to not risk underestimating the number of affected passenger carriers and the corresponding cost of the lease and interchange requirements of the May 2015 final rule.

[14] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Pages 9–12.

(f) The total number of 13,386 passenger carriers shown actually represents 11,705 unique carriers, because some carriers provide passenger service in more than one of the operation classifications shown. Consistent with the approach used in the regulatory evaluation for the May 2015 final rule, the larger number was used here so as to not risk underestimating the number of affected passenger carriers and the corresponding cost of the lease and interchange requirements of the May 2015 final rule.

The 2017 value of 7,774 passenger carriers that would be subject to the 2015 final rule was then used as the basis to develop future projections over the 2019 to 2028 analysis period. These projections were developed by increasing the baseline 2017 value of 7,774 passenger carriers consistent with the occupation-specific employment growth projections for Standard Occupational Classification (SOC) Code 53–3021 (Bus drivers, transit and intercity) obtained from the Bureau of Labor Statistics (BLS) Employment Projections Program which, from 2016 to 2026, is forecast to grow by 0.85 percent annually.[15] This results in a projection of the number of passenger carriers that, in the absence of the proposed rule, would be subject to the 2015 rule each year over the 2019 to 2028 analysis period. In the absence of the proposed rule, all of these passenger carriers would be subject to the 2015 rule. As discussed earlier, under the proposed rule a large portion of these passenger carriers would no longer be subject to lease and interchange requirements, and the remaining carriers would be subject to reduced requirements. In Table 2, the column on the far right shows the projected number of passenger carriers that would experience regulatory relief under the proposed rule over the 10-year analysis period of 2019 to 2028, which equals an annual average of 8,215 passenger carriers.

Table 2 also shows the subset of those 8,215 passenger carriers that under the proposed rule would experience full regulatory relief and would no longer be subject to lease and interchange requirements. Over the 10-year analysis period, the Agency estimates that an annual average of 6,161 passenger carriers, or approximately 75 percent of the total number of carriers that would experience regulatory relief, would experience full regulatory relief. This value was estimated by assuming that approximately 10 percent of authorized for-hire carriers would be subject to the lease and interchange requirements under the proposed rule, rather than 100 percent as assumed previously under the 2015 final rule and as shown in Table 3.

For exempt for-hire carriers and private passenger carriers, the analysis assumes that 100 percent and 10 percent, respectively, of these carriers would continue to be subject to the lease and interchange requirements under the proposed rule, the same percentages as under the 2015 final rule and also as shown in Table 3. Combined, these changes result in an estimated overall reduction of approximately 75 percent in the number of passenger carriers subject to lease and interchange requirements under the proposed rule.[16] This reduction is consistent with the comments and petitions for reconsideration that the Agency received, a number of which suggested that the scope of the 2015 final rule likely encompassed a relatively large proportion of passenger-carrying CMV trips in which both the lessor and the lessee were authorized carriers. Petitioners generally argued that such carriers should not be subject to lease and interchange requirements.

Finally, Table 2 also presents an estimate of the remaining subset of the annual average of 8,215 passenger carriers that would experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 rule. Over the 10-year analysis period, the Agency estimates that an annual average of 2,054 passenger carriers, or approximately 25 percent of the total, would experience partial regulatory relief. As noted earlier, however, these carriers would be subject to reduced requirements compared to those of the 2015 final rule.

FMCSA requests comments and submission of quantitative or qualitative data addressing the potential number of passenger carriers that would experience regulatory relief under the proposed rule.

Number of CMV Trips Experiencing Regulatory Relief Under the Proposed Rule

The Agency estimates that an annual average of 537,134 passenger-carrying CMV trips would experience regulatory relief under the proposed rule over the 10-year analysis period, as presented in Table 4 and discussed below. This estimate is based on the same methods as those developed and used in the evaluation of the 2015 final rule.[17] The estimated number of passenger carriers that would experience regulatory relief under the proposed rule (see Table 2) serves as the primary basis for the estimate of the number of trips that would experience regulatory relief under the proposed rule. For each of the carriers in Table 2, we assumed an estimated average of 64 trips per year are operated with leased or interchanged vehicles. This is consistent with the assumptions used in the regulatory evaluation for the 2015 final rule.[18] The estimated number of trips that would experience regulatory relief under the proposed rule (see Table 4) also incorporates a modest upward adjustment to reflect an annual average of 11,400 trips operated by Greyhound, one of the largest U.S. interstate passenger carriers. This adjustment is consistent with the methods used in the evaluation of the 2015 final rule,[19] and is based on data that was provided to FMCSA by Greyhound regarding trips with leased and interchanged vehicles in 2012.[20]

[15] U.S. DOLBLS. ''Occupational Employment Projections. Table 1.2: Employment by detailed occupation, 2016 and projected 2026.'' Available at: *https://www.bls.gov/emp/ep_data_occupational_data.htm* (accessed December 29, 2017).

[16] As shown in Table 3, in 2017 an estimated 7,774 passenger carriers would be subject to the lease and interchange requirements of passenger-carrying CMVs under the May 2015 final rule. Under the proposed rule, as noted, the analysis assumed that only 10 percent of authorized for-hire carriers would be subject to the lease and interchange requirements of passenger-carrying CMVs, or 10 percent of 6,629, which equals 663 authorized for-hire passenger carriers. The analysis also assumed that 100 percent of exempt for-hire carriers and 10 percent of private passenger carriers would continue to be subject to the lease and interchange requirements for passenger-carrying CMVs under the proposed rule, which equals 100 percent of 340 and 181 exempt for-hire carriers (totaling 521 exempt for-hire carriers), and 10 percent of 2,599 and 3,637 private carriers (totaling 624 private carriers). Therefore, the Agency estimates that 1,808 passenger carriers would be subject to the lease and interchange requirements of passenger-carrying CMVs in 2017 under the proposed rule, or 23.3 percent of those subject to the requirements under the 2015 final rule, which is rounded to 25 percent for purposes of developing the future projections of affected passenger carriers presented in Table 2. This is a 75 percent reduction in the number of passenger carriers affected by the lease and interchange requirements of passenger-carrying CMVs as a consequence of the proposed rule.

[17] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 21, Table 6.

[18] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 21, Table 6.

[19] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Pages 12 to 13.

[20] ''Lease and Interchange of Vehicles; Motor Carriers of Passengers. NPRM.'' September 20, 2013. Comments of Greyhound Lines, Inc.. Docket ID number FMCSA–2012–0103–0010. Page 2. November 12, 2013. Available at: *https://*

Continued

The Agency estimates that approximately 75 percent of these passenger-carrying CMV trips would experience full regulatory relief and would no longer be subject to the lease and interchange requirements of the 2015 final rule. The remaining 25 percent of these trips would experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 final rule.

FMCSA requests comments and submission of quantitative or qualitative data addressing the potential number of passenger-carrying CMV trips that would experience regulatory relief under the proposed rule.

TABLE 4—ESTIMATED NUMBER OF PASSENGER-CARRYING CMV TRIPS EXPERIENCING REGULATORY RELIEF UNDER THE PROPOSED RULE

Year	Passenger-carrying CMV trips experiencing full regulatory relief under the proposed rule	Passenger-carrying CMV trips experiencing partial regulatory relief under the proposed rule	Total CMV trips experiencing regulatory relief under the proposed rule
2019	387,714	129,238	516,952
2020	391,003	130,334	521,337
2021	394,318	131,440	525,758
2022	397,663	132,554	530,217
2023	401,036	133,678	534,714
2024	404,437	134,812	539,249
2025	407,866	135,956	543,822
2026	411,325	137,109	548,434
2027	414,814	138,271	553,085
2028	418,332	139,444	557,776
Annual average	402,851	134,284	537,134

Other Key Inputs to the Analysis

The opportunity cost of the time employees of passenger carriers spend complying with the lease and interchange requirements represents approximately 95 percent of the total cost of the 2015 final rule. The cost savings from the proposed rule are likewise heavily influenced by aggregate changes in the opportunity cost of employee time.

The Agency evaluates changes in employee opportunity cost by using their labor costs. Labor costs comprise wages, fringe benefits, and overhead. Fringe benefits include paid leave, bonuses and overtime pay, health and other types of insurance, retirement plans, and legally required benefits (Social Security, Medicare, unemployment insurance, and workers' compensation insurance). Overhead includes any expenses to a firm associated with labor that are not part of employees' compensation, and typically includes many types of fixed costs of managing a body of employees, such as management and human resource staff salaries or payroll services. The economic costs of labor to a firm, in this case a passenger carrier, include all forms of compensation and labor related expenses. For this regulatory evaluation, the costs of labor to the firm are calculated to include base wages and fringe benefits, plus overhead.

For the regulatory evaluation of both the 2015 final rule and this proposed rule, the median hourly base wage rate for the BLS SOC code 53–1031, ''First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators,'' is used as the basis for calculating the relevant cost of labor. For 2016, BLS reports an hourly base wage rate of $27.54 for this occupation.[21]

BLS does not publish data on fringe benefits for specific occupations, but it does do so for broad industry groups in its Employer Costs for Employee Compensation (ECEC) publication. A fringe benefit rate of 57 percent (*i.e.,* equal to 57 percent of the base wage rate) is used. This is based on information from the June 2016 BLS ECEC data, which for the ''Transportation and warehousing'' segment of private industry reports a benefits cost of $14.09 per hour worked, which represents 57 percent of wages and salaries in that industry segment of $24.73 per hour.[22]

Finally, for estimating overhead rates, the Agency used industry data gathered for the Truck Costing Model developed by the Upper Great Plains Transportation Institute, North Dakota State University.[23] Research conducted for this model found an average cost of $0.107 per mile of CMV operation for management and overhead, and $0.39 per mile for labor, indicating an overhead rate of 27 percent (27% = $0.107 ÷ $0.39 (rounded to the nearest whole percent)).

Combined, the overall relevant cost of labor, including base wage rate, fringe benefits, and overhead, for passenger carriers that would experience regulatory relief under the proposed rule is $54.91 per hour.

Costs

The proposed rule would not result in any increase in costs. It revises the 2015 final rule, which serves as the baseline against which the effects of the proposed rule are evaluated. Absent the proposed rule, the Agency estimates

www.regulations.gov/contentStreamer?documentId=FMCSA-2012-0103-0010&attachmentNumber=1&contentType=pdf (accessed March 12, 2018). Greyhound reported 10,263 passenger-carrying CMV trips performed in 2012 by vehicles leased and interchanged. This 2012 value was then adjusted to reflect observed industry growth from 2012 to 2016 as represented by growth in employment for SOC Code 53–3021 (Bus drivers, transit and intercity), and then further adjusted to reflect employment growth projection for SOC Code 53–3021 (Bus drivers, transit and intercity).

[21] U.S. DOLBLS. ''Occupational Employment Statistics (OES). National.'' May 2016. March 31, 2017. Available at: *https://www.bls.gov/oes/special.requests/oesm16nat.zip* (accessed January 18, 2018).

[22] U.S. DOLBLS . ''Table 10: Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by industry group, March 2015.'' Available at: *https://www.bls.gov/news.release/archives/ecec_09082016.pdf* (accessed March 5, 2017).

[23] Berwick, Farooq. *Truck Costing Model for Transportation Managers.* North Dakota State University. Upper Great Plains Transportation Institute. August 2003. Appendix A, pp. 42–47. Available at: *http://www.mountain-plains.org/pubs/pdf/MPC03-152.pdf* (accessed July 20, 2015).

that the baseline costs of the 2015 final rule over the 10-year analysis period of 2019 to 2028 would be $10.4 million on an annualized basis at a 7 percent discount rate.[24] As noted earlier, the Agency estimates that the proposed rule would result in a cost savings of $8.2 million at a 7 percent discount rate relative to the 2015 baseline, representing a 79 percent overall reduction in cost.

The estimated reduction of approximately 75 percent in the number of passenger carriers and CMV trips under the proposed rule is responsible for most of the annualized cost savings. The remaining cost savings are the result of reduced requirements for those approximately 25 percent of passenger carriers and CMV trips that would remain subject to the lease and interchange rules.

Under both the 2015 rule and the proposed rule, costs are organized into six major categories. Five are related to the requirements under § 390.303 of the 2015 rule, and include: One-time costs of lease negotiation; lease documentation costs; lease copying costs; lease receipt costs; and vehicle marking costs. The sixth cost category is related to the charter party notification requirement under § 390.305 of the 2015 rule.

One-time costs of lease negotiation under the proposed rule are calculated based on the number of CMV trips that would experience regulatory relief under the proposed rule for this cost category, the time expended by employees in negotiating the lease and developing the lease document, and the total labor cost of these employees. The number of trips that would experience regulatory relief under the proposed rule for this cost category are the trips that would no longer be subject to the lease and interchange requirements. As presented earlier in Table 4, the Agency estimates that an annual average of 402,851 passenger-carrying CMV trips would no longer be subject to the lease and interchange requirements. Consistent with the approach used in the 2015 regulatory evaluation, for each of these trips it is assumed that 30 minutes of employee time is saved, for both the lessor and the lessee, for a total time savings of one hour for each such trip.[25] This savings is valued at the total labor cost of $54.91 per hour, described earlier. The resulting savings in one-time costs of lease negotiation under the proposed rule would be $21.3 million on an undiscounted basis over the 10-year analysis period, and $2.8 million on an annualized basis at a 7 percent discount rate. As noted earlier, FMCSA proposes to remove the requirement in § 390.303(b)(5) that the lease contain a statement that the lessee is responsible for compliance with the insurance requirements of 49 CFR part 387. Although in theory this proposed change may result in a modest incremental reduction in the amount of time passenger carrier employees expend in negotiating the lease and developing the lease document for carriers still subject to the leasing and interchange requirements, there is no empirical basis upon which to estimate such a possible impact. Therefore the Agency has chosen not to make any such incremental reduction in its analysis. Also, not quantifying such a potential impact is a conservative approach that helps to avoid overestimating the cost savings of the proposed rule.

Lease documentation costs under the proposed rule are calculated based on the number of CMV trips that would experience regulatory relief under the proposed rule for this cost category, the time spent by carrier employees verifying the information and signing the lease, and the total labor cost of these employees. The number of trips that would experience regulatory relief under the proposed rule for this cost category are the same as above, an annual average of 402,851 trips that would no longer be subject to the lease and interchange requirements. Consistent with the 2015 regulatory evaluation, for each trip that would experience regulatory relief under the proposed rule for this cost category this analysis assumes that both the lessor and the lessee save 5 minutes of employee time, for a total savings of 10 minutes for each such trip.[26] This is valued at the total labor cost of $54.91 per hour. The resulting savings in lease documentation costs under the proposed rule would be $36.9 million on an undiscounted basis over the 10-year analysis period, and $3.7 million on an annualized basis at a 7 percent discount rate.

Lease copying cost savings under the proposed rule are calculated based on the number of CMV trips that would experience regulatory relief under the proposed rule for this cost category, and an estimated cost per copy. The number of trips that would experience regulatory relief under the proposed rule for this cost category are the same as above, an annual average of 402,851 such trips. As in the 2015 regulatory evaluation, it assumed that for each trip one copy of the lease is made for the lessor and another for the lessee, each at a cost of $0.15, for a total cost of $0.30 per trip.[27] The resulting in lease copying cost savings under the proposed rule would be $1.2 million on an undiscounted basis over the 10-year analysis period, and $0.12 million on an annualized basis at a 7 percent discount rate.

The remaining three cost categories (lease receipts, vehicle marking, and charter party notification) would be eliminated for all passenger carriers and passenger-carrying trips, including those that would still be subject to lease and interchange requirements under the proposed rule.

Lease receipt cost savings under the 2015 rule are calculated based on the number of CMV trips that would experience regulatory relief under the proposed rule for this cost category, with two receipts assumed per trip (one for obtaining, the other for surrendering the vehicle), and both the lessor and lessee requiring copies of each, for a total of four receipts per trip. Because the proposed rule would remove the receipt provision in its entirety, the cost savings would apply to all trips listed in Table 4, an annual average of 537,134 trips. Consistent with the 2015 regulatory evaluation, each receipt is assumed to cost $0.15, with four receipts required for a total of $0.60 per trip.[28] The resulting cost savings in lease receipt under the proposed rule would be $3.2 million on an undiscounted basis over the 10-year analysis period, and $0.321 million on an annualized basis at a 7 percent discount rate.

Vehicle marking cost savings under the 2015 rule are calculated based on the number of CMV trips that would experience regulatory relief under the proposed rule for this cost category, and marking costs per vehicle that include two sheets of letter size paper per trip at $0.014 per sheet, plus $0.04 for

[24] This annualized cost estimate of $10.4 million differs somewhat from the value of $8.0 million that was presented in the regulatory evaluation for the 2015 final rule primarily due to various real and nominal updates made to reflect more recently available data and information, as well as the different time frames covered by the 10-year analysis period for each respective analysis (previously 2017 to 2026, and now 2019 to 2028).

[25] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Pages 16 to 17.

[26] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 17.

[27] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 17.

[28] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 17 to 18.

adhesive tape. Because the proposed rule would remove the marking provision in its entirety, the cost savings would apply to all trips listed in Table 4, an annual average of 537,134 trips. The resulting cost savings in vehicle marking under the proposed rule would be $0.355 million on an undiscounted basis over the 10-year analysis period, and $0.035 million on an annualized basis at a 7 percent discount rate.

Charter party notification cost savings under the 2015 rule are calculated based on the number of CMV trips that would experience regulatory relief under the proposed rule for this cost category, and an estimated expenditure by passenger carrier employees of 5 minutes per notification.[29] Because the proposed rule would remove the notification provision in its entirety, the resulting cost savings would apply to all trips in which notification would otherwise have been necessary, which are assumed to be 50 percent of the total annual average of 537,134 passenger-carrying CMV trips listed in Table 4.[30] The resulting savings in charter party notification costs under the proposed rule would be $12.1 million on an undiscounted basis over the 10-year analysis period, and $1.2 million on an annualized basis at a 7 percent discount rate.

In summary, and as presented in Table 5, the Agency estimates that the proposed rule would result in a cost savings of $75.1 million on an undiscounted basis, $66.5 million discounted at 3 percent, and $57.5 million discounted at 7 percent over the 10-year analysis period. Expressed on an annualized basis, this equates to a 10-year cost savings of $7.8 million at a 3 percent discount rate and $8.2 million at a 7 percent discount rate.

TABLE 5—TOTAL COST OF THE PROPOSED RULE

[In thousands of 2016$]

Year	Undiscounted					Discounted	
	Lease and interchange costs			Charter party notification costs	Total cost [a]	Discounted at 3%	Discounted at 7%
	Lease negotiation costs [b]	Lease documentation, copying, and lease receipt costs	Vehicle marking costs				
2019	($21,290)	($3,974)	($34)	($1,168)	($26,467)	($25,697)	($24,736)
2020	0	(4,008)	(34)	(1,178)	(5,221)	(4,921)	(4,560)
2021	0	(4,042)	(35)	(1,188)	(5,265)	(4,819)	(4,298)
2022	0	(4,076)	(35)	(1,198)	(5,310)	(4,718)	(4,051)
2023	0	(4,111)	(35)	(1,208)	(5,355)	(4,619)	(3,818)
2024	0	(4,146)	(36)	(1,219)	(5,401)	(4,523)	(3,599)
2025	0	(4,181)	(36)	(1,229)	(5,446)	(4,428)	(3,392)
2026	0	(4,216)	(36)	(1,239)	(5,493)	(4,336)	(3,197)
2027	0	(4,252)	(37)	(1,250)	(5,539)	(4,245)	(3,013)
2028	0	(4,289)	(37)	(1,261)	(5,586)	(4,157)	(2,840)
Total	(21,290)	(41,301)	(355)	(12,139)	(75,084)	(66,463)	(57,504)
Annualized					(7,508)	(7,792)	(8,187)

Notes:

(a) Total cost values may not equal the sum of the components due to rounding. (The totals shown in this column are the rounded sum of unrounded components.)

(b) Values shown in parentheses are negative values (*i.e.,* less than zero) and represent a decrease in cost or a cost savings.

Benefits

The regulatory evaluation for the 2015 final rule attempted to estimate the potential safety benefits of lease and interchange requirements,[31] but there were insufficient data and empirical evidence to demonstrate a measurable quantitative relationship between lease and interchange requirements and improved safety outcomes, such as reduced frequency and/or severity of crashes or reduced frequency of violations. Therefore, FMCSA followed the guidance of the Office of Management and Budget (OMB) in its Circular A–4 and performed a threshold analysis.[32] Also referred to as a break-even analysis, a threshold analysis attempts to determine the amount of safety benefits (*e.g.,* reduced crashes and corresponding reductions in fatalities, injuries, and property damage) that would need to occur as a consequence of a rule in order for the rule to yield zero net benefits (*i.e.,* for the benefits of the rule to equal, or exactly to offset, the estimated costs of the rule).

The problem of insufficient data and empirical evidence noted in 2015 is still present today. Unlike regulations dealing with vehicle equipment or driver behaviors that can be clearly linked to reduced crashes and improved safety, both the 2015 final rule and this proposed rule affect safety less directly and immediately. Lease and interchange requirements for motor carriers of passengers improve the ability of the Agency to attribute the inspection, compliance, enforcement, and safety data collected by the Agency and its State partners to the correct motor carrier and driver, allowing FMCSA to more accurately identify unsafe carriers and initiate appropriate interventions. FMCSA believes that this proposed rule would be a less costly and burdensome regulatory approach than the 2015 final rule, yet would still enable safety officials and the general public to

[29] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 24 to 26.

[30] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.'' Page 24 to 26.

[31] DOT FMCSA, ''Lease and Interchange of Vehicles, Motor Carriers of Passengers, 2015 Final Rule Regulatory Evaluation.''

[32] OMB. ''Circular A–4. Regulatory Analysis.'' September 17, 2003. Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf* (accessed March 9, 2018).

sufficiently identify the passenger carrier responsible for safety. Therefore, the Agency does not anticipate any change to safety benefits as a result of the proposed rule.

FMCSA requests comments and submission of quantitative or qualitative data addressing the potential impacts to safety benefits from the proposed rule.

B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rulemaking is expected to be an E.O. 13771 deregulatory action.[33] Details on the estimated cost savings of this rulemaking can be found in the rule's economic analysis. The present value of the cost savings of this rulemaking, measured on an infinite time horizon at a 7 percent discount rate, is $83.6 million. Expressed on an annualized basis, the cost savings are $5.9 million. These values are expressed in 2016 dollars.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121, 110 Stat. 857), requires Federal agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment. The term ''small entities'' means small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000.[34] Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these entities. Section 605 of the RFA allows an Agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The proposed rule would not result in any increase in costs or any increase in burden. The proposed rule would reduce the applicability of the lease and interchange requirements for motor carriers of passengers, resulting in a substantial reduction in the number of entities that would be subject to these requirements and a commensurate reduction in costs and burden experienced by these entities. Furthermore, for those motor carriers of passengers that would continue to be subject to the lease and interchange requirements under the proposed rule, the requirements would be reduced in comparison to the existing requirements. This would also result in a reduction in costs and burden experienced by these entities.

The regulated entities that would experience regulatory relief under the proposed rule include all of the passenger carriers that are subject to the existing lease and interchange requirements. Approximately 75 percent of this total number of passenger carriers would experience full regulatory relief, and would no longer be subject to lease and interchange requirements for passenger-carrying CMVs. The remaining 25 percent of these passenger carriers would experience partial regulatory relief and remain subject to reduced lease and interchange requirements compared to those of the 2015 final rule.

As presented earlier in Table 3 of the Regulatory Analyses section, as of 2017 there were an estimated 7,774 passenger carriers subject to the existing lease and interchange requirements, representing approximately 58 percent of all active interstate passenger carriers. As presented in Table 2, this population of passenger carriers is projected to increase slightly due to general baseline industry growth to 7,906 passenger carriers in 2019, the first year that the proposed rule is anticipated to be in effect. Therefore, it is estimated that 7,906 passenger carriers would experience regulatory relief under the proposed rule. The number of these 7,906 passenger carriers that are small entities is not directly known by FMCSA, and is therefore estimated below.

The U.S. Small Business Administration (SBA) defines the size standards used to classify entities as small. SBA establishes separate standards for each industry, as defined by the North American Industry Classification System (NAICS).[35] It is estimated that the passenger carriers that would experience regulatory relief under the proposed rule would be in industries within Subsector 485 (Transit and Ground Passenger Transportation). All eleven 6-digit NAICS industries within Subsector 485 have an SBA size standard based on annual revenue of $15.0 million. Three of the eleven 6-digit NAICS industries within Subsector 485 are likely to encompass most of the passenger carriers that would experience regulatory relief under the proposed rule, and details regarding the SBA size standards for those three industries are presented in Table 6.

TABLE 6—SBA SIZE STANDARDS FOR SELECTED INDUSTRIES [(a)]

NAICS code	NAICS industry description	SBA size standard (annual revenue in millions of dollars)	SBA size standard (number of employees)
485113	Bus and Other Motor Vehicle Transit Systems	$15.0	(none).
485210	Interurban and Rural Bus Transportation	15.0	(none).
485510	Charter Bus Industry	15.0	(none).

Notes:
(a) U.S. Small Business Administration (SBA). ''Table of Small Business Size Standards.'' October 1, 2017. Available at: *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.xlsx* (accessed March 20, 2018).

Data regarding the annual revenue earned by the estimated 7,906 passenger carriers that would experience regulatory relief under the proposed rule is not collected by FMCSA and is not otherwise available from other

[33] Executive Office of the President. *Executive Order 13771 of January 30, 2017. Reducing Regulation and Controlling Regulatory Costs.* 82 FR 9339–9341. Feb. 3, 2017.

[34] Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601 *et seq.*).

[35] OMB. ''North American Industry Classification System.'' 2017. Available at: *https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf* (accessed March 20, 2018).

sources. Therefore, the SBA size standard of $15.0 million in annual revenue cannot be directly applied in order to determine how many of the 7,906 passenger carriers that would experience regulatory relief under the proposed rule are small entities. FMCSA does, however, collect information regarding the number of passenger-carrying vehicles operated by these carriers. As of the end of 2017, of the active interstate passenger carriers operating in the U.S. as presented earlier in Table 3, approximately 81 percent operated six or fewer passenger vehicles, and approximately 93 percent operated 19 or fewer passenger vehicles.[36] We estimate that in the passenger carrier industry, the average revenue earned per motorcoach is approximately $200,000.[37] [38] [39] This would mean that the SBA size standard of $15.0 million in annual revenue would equate to a carrier size of 75 passenger vehicles. Therefore, carriers operating 75 passenger vehicles or fewer would be classified as small, consistent with the SBA size standard of $15.0 million. As of the end of 2017, of the active interstate passenger carriers operating in the U.S. as presented earlier in Table 3, approximately 98 percent operated 75 or fewer passenger vehicles. The Agency does not believe that the proposed rule would disproportionately apply to either larger or smaller passenger carriers, and we therefore estimate that a similar 98 percent of the 7,906 passenger carriers that would experience regulatory relief under the proposed rule, or approximately 7,750 passenger carriers, would be small entities. Therefore, FMCSA has determined that this proposed rule will have an impact on a substantial number of small entities.

Although FMCSA has determined that this proposed rule would have an impact on a substantial number of small entities, the Agency has determined that the impact on the small entities that would experience regulatory relief under the proposed rule would not be significant. The proposed rule would not result in any increase in costs or any increase in burden for passenger carriers that are small entities. The effect of the proposed rule would be a reduction in costs and burden, and would be entirely beneficial to the passenger carriers that are small entities. As discussed in the Regulatory Analyses section, the Agency estimates that the proposed rule would result in a total cost savings of $75.1 million on an undiscounted basis over the 10-year analysis period used for the regulatory evaluation, or $7.5 million on an annualized basis. As presented in Table 2, an annual average of approximately 8,215 passenger carriers would experience regulatory relief under the proposed rule over the same 10-year analysis period, 98 percent of which are estimated to be small entities. The annual cost savings per small carrier would therefore be at most $914 on average (potentially even somewhat less, given that approximately 2 percent of passenger carriers that would experience regulatory relief under the proposed rule are not small entities and therefore may represent a disproportionately larger share of the overall absolute cost savings because of the larger scale of their operations). For even the smallest of the small entities, those operating only one passenger vehicle, this $914 in annual savings represents only about one half of one percent of the estimated total annual revenues of $200,000 for a carrier with just one vehicle. Therefore, although FMCSA has determined that this proposed rule would have an impact on a substantial number of small entities, the Agency has also determined that the impact on these small entities would not be significant, and furthermore will be entirely beneficial.

Accordingly, pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), I hereby certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. FMCSA requests comments on this certification and on the analysis presented in support of it.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction, and you have questions concerning its provisions or options for compliance, please consult the FMCSA point of contact, Ms. Loretta Bitner, listed in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's 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 FMCSA, call 1–888–REG–FAIR (1–888–734–3247). The DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.[40]

E. Unfunded Mandates Reform Act of 1995

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 requires agencies to prepare a comprehensive written statement for any proposed or final rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $156 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2015 levels) or more in any one year. Because this proposed rule would not result in such an expenditure, a written statement is not required. However, the Agency does discuss the costs and benefits of this

[36] U.S. DOT, FMCSA. Motor Carrier Management Information System (MCMIS), and Licensing and Insurance (L&I) system. Snapshots as of December 29, 2017 (DART request ID #38883).

[37] The information available regarding revenue for the passenger carrier industry is limited. The American Bus Associated reported that for 2004, revenue per motorcoach was approximately $160,000. Inflated from 2004 dollars to 2016 dollars using either CPI–U or the Implicit Price Deflator for GDP, this value becomes approximately $200,000 per vehicle.

[38] American Bus Association (ABA). ''Motorcoach Census 2005.'' September 2006. Page 19, Table 3–5 (Carrier Revenue per Motorcoach, Averages, 2004). Available at: *https://www.iru.org/apps/cms-filesystem-action?file=events_2007_busandcoach/Motorcoach%20Census%202005%2009-21-20061.pdf* (accessed March 8, 2018).

[39] Greyhound, one of the largest interstate passenger carriers operating in the U.S., reported total revenue for 2017 of $894 million, with 78 percent of that total, or $697 million, being passenger revenue. With a fleet size reported to consist of 1,600 buses for the same year, this equals an average passenger revenue per motorcoach of $435,000. We believe that substantially higher levels of per vehicle revenue such as this are not representative of the smaller passenger carriers that make up most of the industry, and therefore the lesser estimate of $200,000 revenue per motorcoach described above was used here so as not to risk underestimating the number of small entities in the passenger carrier industry when used to compare against the SBA size standard of $15.0 million in annual revenue. Greyhound data is from ''FirstGroup plc, Annual Report and Accounts, 2017'', pages 18–19, available at *http://www.firstgroupplc.com/–/media/Files/F/Firstgroup-Plc/indexed-pdfs/2017%20ARA/2017%20FirstGroup%20plc%20Annual%20Report%20and%20Accounts.pdf* (accessed March 19, 2018).

[40] U.S. Department of Transportation (DOT). ''The Rights of Small Entities To Enforcement Fairness and Policy Against Retaliation.'' Available at: *https://www.transportation.gov/sites/dot.gov/files/docs/SBREFAnotice2.pdf* (accessed January 17, 2018).

proposed rule elsewhere in this preamble.

F. Paperwork Reduction Act

This proposed rule would amend two OMB-approved information collections titled ''Commercial Motor Vehicle Marking Requirements,'' OMB No. 2126–0054, and ''Lease and Interchange of Vehicles,'' OMB No. 2126–0056, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), ''collection of information'' includes reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

The Agency's CMV marking regulations require freight-carrying commercial motor carriers, passenger-carrying commercial motor carriers, and intermodal equipment providers to display the USDOT number and the legal name or a single trade name of the carrier or intermodal equipment provider on their vehicles. The USDOT number is used to identify all motor carriers in FMCSA's registration and information systems. It is also used by States as the key identifier in the Performance and Registration Information Systems Management (PRISM) system, a cooperative Federal/State program that makes motor carrier safety a requirement for obtaining and maintaining CMV registration and privileges. Vehicle marking requirements are intended to ensure that FMCSA, the National Transportation Safety Board (NTSB), and State safety officials are able to identify motor carriers and correctly assign responsibility for regulatory violations during inspections, investigations, compliance reviews, and crash studies. These marking requirements also provide the public with beneficial information that could assist in identifying carriers for the purposes of commerce, complaints, or emergency notification.

The proposed rule would eliminate the existing requirement under 49 CFR 390.303(f) for the temporary marking of leased commercial passenger vehicles. The proposed rule would therefore amend the OMB-approved information collection titled ''Commercial Motor Vehicle Marking Requirements,'' OMB No. 2126–0054. In the currently approved information collection, the temporary marking of leased commercial passenger vehicles was assumed to have *de minimis* time burden, and therefore no separate time burden was estimated for that element of the passenger-carrying commercial motor carrier marking requirements. Because of this, in the proposed revision to this information collection, there is no change in time burden due to program change, and the estimated changes in time burden from the currently approved information collection are due to adjustments related to factors such as revised estimates of the population of passenger-carrying motor carriers and industry growth rate. There is a small reduction in the annual cost burden, however, related to the elimination of the cost of materials (paper and adhesive tape) estimated to be used for the temporary vehicle markings that are proposed to be eliminated.

Title: Commercial Motor Vehicle Marking Requirements.

OMB control number: 2126–0054.

Summary of the collection of information: Under the information collection, freight-carrying commercial motor carriers, passenger-carrying commercial motor carriers, and intermodal equipment providers mark their vehicles to display the USDOT number and the legal name or a single trade name of the carrier or intermodal equipment provider. This vehicle marking occurs when a new vehicle is purchased, when a used vehicle is purchased and requires re-marking, and when a vehicle is retained by the owner but the existing label reaches the end of its useful life.

Need for information: Vehicle marking requirements are needed to ensure that FMCSA, the NTSB, and State safety officials are able to identify motor carriers and correctly assign responsibility for regulatory violations during inspections, investigations, compliance reviews, and crash studies. These marking requirements also provide the public with beneficial information that could assist in identifying carriers for the purposes of commerce, complaints, or emergency notification.

Proposed use of information: The USDOT number is used to identify all motor carriers in FMCSA's registration and information systems, is used as the key identifier in the PRISM system, and is used by the public with beneficial information that could also assist in identifying carriers for the purposes of commerce, complaints, or emergency notification.

Description of the respondents: Freight-carrying commercial motor carriers, passenger-carrying commercial motor carriers, and intermodal equipment providers.

Number of respondents:

IC–1 (freight carriers) number of respondents: 204,390

IC–2 (passenger carriers) number of respondents: 5,007

IC–3 (intermodal equipment providers) number of respondents: 11

Total number of respondents: 209,408

Frequency of response:

IC–1 (freight carriers) frequency of response: 7.9 responses per year, per respondent

IC–2 (passenger carriers) frequency of response: 20.4 responses per year, per respondent

IC–3 (intermodal equipment providers) frequency of response: 1,910 responses per year, per respondent

Overall average frequency of response: 8.3 response per year, per respondent

Burden of response:

IC–1 (freight carriers) burden of response: 0.43 hours

IC–2 (passenger carriers) burden of response: 0.43 hours

IC–3 (intermodal equipment providers) burden of response: 0.43 hours

Overall average burden of response: 0.43 hours

Estimate of Total Annual Burden:

IC–1 (freight carriers) burden: 699,902 hours

IC–2 (passenger carriers) burden: 44,300 hours

IC–3 (intermodal equipment providers) burden: 9,108 hours

Total annual burden: 753,310 hours

The Agency's lease and interchange of vehicles regulations ensure that truck and bus carriers are identified (and in some cases protected) when they agree to lease their equipment and drivers to other carriers. These regulations also ensure that the government and members of the public can determine who is responsible for a CMV. Prior to these regulations, some equipment was leased without written agreements, leading to disputes and confusion over which party to the lease was responsible for charges and actions and, at times, who was legally responsible for the vehicle. These recordkeeping requirements enable the general public and investigators to identify the passenger carrier responsible for safety, and ensure that FMCSA, our State partners, and the NTSB are better able to identify the responsible motor carrier and therefore correctly assign regulatory violations to the appropriate carrier during inspections, investigations, compliance reviews, and crash studies.

The proposed rule would reduce the scope of the lease and interchange requirements for motor carriers of passengers. Furthermore, those passenger carriers and passenger-carrying CMV trips for which the proposed rule would remain applicable would be subject to lease and interchange requirements that are reduced from the current requirements. The applicability of the existing lease and interchange requirements for motor carriers of passengers under 49 CFR 390.301 would be revised, resulting in a substantial reduction of approximately 75% in the number of passenger carriers and passenger-carrying CMV trips that would be subject to the lease and interchange requirement for motor carriers of passengers. For those motor carriers of passengers that would remain subject to the lease and interchange requirements under the proposed rule, the existing requirements under 49 CFR 390.303(e) for lease receipt copies would be eliminated, and the existing requirements under 49 CFR 390.305 for charter party notification would also be eliminated.

The proposed rule would therefore amend the OMB-approved information collection titled ''Lease and Interchange of Vehicles,'' OMB No. 2126–0056. In the proposed revision to this information collection, there is substantial reduction in time burden due to program change from the currently approved information collection as a result of the proposed rule.

Title: Lease and Interchange of Vehicles

OMB control number: 2126–0056.

Summary of the collection of information: Under the information collection, freight-carrying commercial motor carriers and passenger-carrying commercial motor carriers negotiate leases, prepare and sign lease documents, and produce copies of lease documents.

Need for information: The Agency's lease and interchange of vehicles regulations ensure that truck and bus carriers are identified (and in some cases protected) when they agree to lease their equipment and drivers to other carriers. These regulations also ensure that the government and members of the public can determine who is responsible for a CMV. These recordkeeping requirements enable the general public and investigators to identify the passenger carrier responsible for safety.

Proposed use of information: The government generally collects little information with this ICR. The leases and other agreements are developed and held by the lessor (*e.g.,* those granting use of equipment) and lessee (*e.g.,* party acquiring equipment). They are used to assign duties and responsibilities. The information may also be used by law enforcement to determine legal responsibility in the event that a leased vehicle is in violation of the regulations or is involved in a crash.

Description of the respondents: Freight-carrying commercial motor carriers, and passenger-carrying commercial motor carriers.

Number of respondents:

IC–1 (property-carrying CMVs) number of respondents: 35,902

IC–2 (passenger-carrying CMVs) number of respondents: 3,987

Total number of respondents: 39,889

Frequency of response:

IC–1 (property-carrying CMVs) frequency of response: 19.9 responses per year, per respondent

IC–2 (passenger-carrying CMVs) frequency of response: 152.4 responses per year, per respondent

Overall average frequency of response: 33.2 response per year, per respondent

Burden of response:

IC–1 (property-carrying CMVs) burden of response: 0.11 hours

IC–2 (passenger-carrying CMVs) burden of response: 0.11 hours

Overall average burden of response: 0.11 hours

Estimate of total annual burden:

IC–1 (property-carrying CMVs) burden: 77,554 hours

IC–2 (passenger-carrying CMVs) burden: 64,802 hours

Total annual burden: 142,356 hours

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), FMCSA will submit a copy of this proposed rule to OMB for its review of the collection of information.

FMCSA asks for public comment on the proposed collection of information to help us determine how useful the information is; whether it can help the Agency perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining burden are; how FMCSA can improve the quality, usefulness, and clarity of the information; and how FMCSA can minimize the burden of collection.

G. E.O. 13132 (Federalism)

A rule has implications for Federalism under Section 1(a) of E.O. 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' FMCSA determined that this proposal would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Impact Statement.

H. E.O. 12988 (Civil Justice Reform)

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

I. E.O. 13045 (Protection of Children)

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this proposed rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

J. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this proposed rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it would not effect a taking of private property or otherwise have taking implications.

K. Privacy

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a Privacy Impact Assessment (PIA) of a regulation that will affect the privacy of individuals. This proposed rule does not require the collection of any personally identifiable information.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program. FMCSA has

determined that this rule would not result in a new or revised Privacy Act System of Records for FMCSA.

The E–Government Act of 2002, Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (December 17, 2002), requires Federal agencies to conduct a PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information as a result of this rule. Accordingly, FMCSA has not conducted a privacy impact assessment.

L. E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

M. E.O. 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

N. E.O. 13783 (Promoting Energy Independence and Economic Growth)

Executive Order 13783 directs executive departments and agencies to review existing regulations that potentially burden the development or use of domestically produced energy resources, and to appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources.[41] In accordance with E.O. 13783, the DOT prepared and submitted a report to the Director of OMB providing specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency action that burden domestic energy production. The DOT has not identified this proposed rule as potentially alleviating unnecessary burdens on domestic energy production under E.O. 13783.

[41] Exec. Order No. 13783, 82 FR 16093 (March 31, 2017).

O. E.O. 13175 (Indian Tribal Governments)

This rule does not have tribal implications under E.O. 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.

P. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) 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 (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

Q. Environment (NEPA and CAA)

FMCSA analyzed this NPRM for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, March 1, 2004), Appendix 2, paragraphs (6)(y)(2) and (6)(y)(7). The Categorical Exclusion (CE) in paragraph (6)(y)(2) covers regulations implementing motor carrier identification and registration reports. The Categorical Exclusion (CE) in paragraph (6)(y)(7) covers regulations implementing prohibitions on motor carriers, agents, officers, representatives, and employees from making fraudulent or intentionally false statements on any application, certificate, report, or record required by FMCSA. The proposed requirements in this rule are covered by these CEs, and the proposed action does not have the potential to significantly affect the quality of the environment. The CE determination is available for inspection or copying in the *regulations.gov* website listed under **ADDRESSES**.

FMCSA also analyzed this rule under section 176(c) of the Clean Air Act, as amended (CAA) (42 U.S.C. 7401 *et seq.*), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement since it does not affect direct or indirect emissions of criteria pollutants.

List of Subjects in 49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, FMCSA proposes to amend 49 CFR chapter III, subchapter B, part 390 to read as follows:

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 1. The authority citation for part 390 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31134, 31136, 31137, 31144, 31149, 31151, 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 212 and 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as added and transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743; sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; secs. 32101(d) and 32934, Pub. L. 112–141, 126 Stat. 405, 778, 830; sec. 2, Pub. L. 113–125, 128 Stat. 1388; secs. 5403, 5518, and 5524, Pub. L. 114–94, 129 Stat. 1312, 1548, 1558, 1560; sec. 2, Pub. L. 115–105, 131 Stat. 2263; and 49 CFR 1.81, 1.81a, 1.87.

■ 2. Amend § 390.5 as follows:
■ a. Lift the suspension of the section;
■ b. Revise the definition of ''*Lease,*'' ''*Lessee,*'' and ''*Lessor*'' in alphabetical order'';
■ c. Suspend § 390.5 indefinitely.

The revised text reads as follows:

§ 390.5 Definitions.

* * * * *

Lease, as used in subpart G of this part, means a contract or agreement in which a motor carrier of passengers grants the use of a passenger-carrying commercial motor vehicle to another motor carrier, with or without a driver, for a specified period for the transportation of passengers, whether or not compensation for such use is specified or required, when one of the motor carriers of passengers is not authorized to operate in interstate commerce pursuant to 49 U.S.C. 13901–13902. The term *lease* includes an interchange, as defined in this section, or other agreement granting the use of

a passenger-carrying commercial motor vehicle for a specified period, with or without a driver, whether or not compensation for such use is specified or required. For a definition of *lease* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessee, as used in subpart G of this part, means the motor carrier obtaining the use of a passenger-carrying commercial motor vehicle through a *lease* as defined in this section, with or without the driver, from another motor carrier. The term *lessee* includes a motor carrier obtaining the use of a passenger-carrying commercial motor vehicle from another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of *lessee* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessor, as used in subpart G of this part, means the motor carrier granting the use of a passenger-carrying commercial motor vehicle through a *lease* as defined in this section, with or without a driver, to another motor carrier. The term *lessor* includes a motor carrier granting the use of a passenger-carrying commercial motor vehicle to another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of *lessor* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

* * * * *

■ 3. Amend § 390.5T by revising the definitions of ''Lease,'' ''Lessee,'' and ''Lessor'' in alphabetical order to read as follows:

§ 390.5T Definitions.

* * * * *

Lease, as used in subpart G of this part, means a contract or agreement in which a motor carrier of passengers grants the use of a passenger-carrying commercial motor vehicle to another motor carrier, with or without a driver, for a specified period for the transportation of passengers, whether or not compensation for such use is specified or required, when one of the motor carriers of passengers is not authorized to operate in interstate commerce pursuant to 49 U.S.C. 13901–13902. The term *lease* includes an interchange, as defined in this section, or other agreement granting the use of a passenger-carrying commercial motor vehicle for a specified period, with or without a driver, whether or not compensation for such use is specified or required. For a definition of *lease* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessee, as used in subpart G of this part, means the motor carrier obtaining the use of a passenger-carrying commercial motor vehicle through a *lease* as defined in this section, with or without the driver, from another motor carrier. The term *lessee* includes a motor carrier obtaining the use of a passenger-carrying commercial motor vehicle from another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of *lessee* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

Lessor, as used in subpart G of this part, means the motor carrier granting the use of a passenger-carrying commercial motor vehicle through a *lease* as defined in this section, with or without a driver, to another motor carrier. The term *lessor* includes a motor carrier granting the use of a passenger-carrying commercial motor vehicle to another motor carrier under an interchange or other agreement, with or without a driver, whether or not compensation for such use is specified. For a definition of *lessor* in the context of property-carrying vehicles, see § 376.2 of this subchapter.

* * * * *

■ 4. Amend § 390.21 as follows:
■ a. Lift the suspension of the section;
■ b. Revise paragraph (e);
■ c. Remove paragraph (f);
■ d. Redesignate paragraphs (g) and (h) as paragraphs (f) and (g), respectively;
■ e. Suspend § 390.21 indefinitely.

The revised text reads as follows:

§ 390.21 Marking of self-propelled CMVs and intermodal equipment.

* * * * *

(e) *Rented CMVs and leased passenger-carrying CMVs.* A motor carrier operating a self-propelled CMV under a rental agreement or a passenger-carrying CMV under a lease, when the rental agreement or lease has a term not in excess of 30 calendar days, meets the requirements of this section if:

(1) The CMV is marked in accordance with the provisions of paragraphs (b) through (d) of this section; or

(2) Except as provided in paragraph (e)(2)(v), the CMV is marked as set forth in paragraph (e)(2)(i) through (iv) of this section:

(i) The legal name or a single trade name of the lessor is displayed in accordance with paragraphs (c) and (d) of this section.

(ii) The lessor's identification number preceded by the letters ''USDOT'' is displayed in accordance with paragraphs (c) and (d) of this section; and

(iii) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee conspicuously contains the following information:

(A) The name and complete physical address of the principal place of business of the renting motor carrier or lessee;

(B) The identification number issued to the renting motor carrier or lessee by FMCSA, preceded by the letters ''USDOT,'' if the motor carrier has been issued such a number. In lieu of the identification number required in this paragraph, the following information may be shown in a rental agreement:

(*1*) Whether the motor carrier is engaged in ''interstate'' or ''intrastate'' commerce; and

(*2*) Whether the renting motor carrier is transporting hazardous materials in the rented CMV;

(C) The sentence: ''This lessor cooperates with all Federal, State, and local law enforcement officials nationwide to provide the identity of customers who operate this rental CMV''; and

(iv) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee is carried on the rental CMV or leased passenger-carrying CMV during the full term of the rental agreement or lease. See the property-carrying leasing regulations at 49 CFR part 376 and the passenger-carrying leasing regulations at subpart G of this part for information that should be included in all leasing documents.

(v) *Exception.* The passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) of this part does not need to comply with paragraphs (iii) and (iv) of this section, provided the lessor and lessee comply with the requirements of § 390.403(a)(2).

* * * * *

■ 5. Amend § 390.21T by
■ a. Revising paragraph (e);
■ b. Removing paragraph (f);
■ c. Redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

The revision to read as follows:

§ 390.21T Marking of self-propelled CMVs and intermodal equipment.

* * * * *

(e) *Rented CMVs and leased passenger-carrying CMVs.* A motor carrier operating a self-propelled CMV under a rental agreement or a passenger-carrying CMV under a lease, when the

rental agreement or lease has a term not in excess of 30 calendar days, meets the requirements of this section if:

(1) The CMV is marked in accordance with the provisions of paragraphs (b) through (d) of this section; or

(2) Except as provided in paragraph (e)(2)(v), the CMV is marked as set forth in paragraph (e)(2)(i) through (iv) of this section:

(i) The legal name or a single trade name of the lessor is displayed in accordance with paragraphs (c) and (d) of this section.

(ii) The lessor's identification number preceded by the letters ''USDOT'' is displayed in accordance with paragraphs (c) and (d) of this section; and

(iii) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee conspicuously contains the following information:

(A) The name and complete physical address of the principal place of business of the renting motor carrier or lessee;

(B) The identification number issued to the renting motor carrier or lessee by FMCSA, preceded by the letters ''USDOT,'' if the motor carrier has been issued such a number. In lieu of the identification number required in this paragraph, the following information may be shown in a rental agreement:

(*1*) Whether the motor carrier is engaged in ''interstate'' or ''intrastate'' commerce; and

(*2*) Whether the renting motor carrier or lessee is transporting hazardous materials in the rented or leased CMV;

(C) The sentence: ''This lessor cooperates with all Federal, State, and local law enforcement officials nationwide to provide the identity of customers who operate this rental or leased CMV''; and

(iv) The rental agreement or lease as applicable entered into by the lessor and the renting motor carrier or lessee is carried on the rental CMV or leased passenger-carrying CMV during the full term of the rental agreement or lease. See the property-carrying leasing regulations at 49 CFR part 376 and the passenger-carrying leasing regulations at subpart G of this part for information that should be included in all leasing documents.

(v) *Exception.* The passenger-carrying CMV operating under the 48-hour emergency exception pursuant to § 390.403(a)(2) of this part does not need to comply with paragraphs (iii) and (iv) of this section, provided the lessor and lessee comply with the requirements of § 390.403(a)(2).

* * * * *

Subpart F—[Removed and Reserved]

■ 6. Remove and reserve subpart F of part 390., consisting of §§ 390.301 through 390.305, to read as follows:

■ 7. Add subpart G, consisting of §§ 390.401 and 390.403, to read as follows:

Subpart G—Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

Sec.

Subpart G—Lease and Interchange of Passenger-Carrying Commercial Motor Vehicles

§ 390.401 Applicability.

(a) *General.* Except as provided in paragraphs (b)(1) and (2) of this section, this subpart applies to the following actions, irrespective of duration, or the presence or absence of compensation, by motor carriers operating commercial motor vehicles to transport passengers:

(1) The lease of passenger-carrying commercial motor vehicles; and

(2) The interchange of passenger-carrying commercial motor vehicles between motor carriers.

(b) *Exceptions*—(1) *Contracts and agreements between motor carriers of passengers with active passenger carrier operating authority registrations.* This subpart does not apply to contracts and agreements between motor carriers of passengers that have active passenger carrier operating authority registrations with the Federal Motor Carrier Safety Administration when one such motor carrier acquires transportation service(s) from another such motor carrier(s).

(2) *Financial leases.* This subpart does not apply to a contract (however designated, *e.g.,* lease, closed-end lease, hire purchase, lease purchase, purchase agreement, installment plan, etc.) between a motor carrier and a financial organization or a manufacturer or dealer of passenger-carrying commercial motor vehicles allowing the motor carrier to use the passenger-carrying commercial motor vehicle.

(c) *Penalties.* If the use of a passenger-carrying commercial motor vehicle is conferred on one motor carrier subject to this subpart by another such motor carrier without a lease or interchange agreement, or pursuant to a lease or interchange agreement that fails to meet all applicable requirements of subpart G, both motor carriers shall be subject to a civil penalty.

§ 390.403 Lease and interchange requirements.

Except as provided in § 390.401(b) of this section, a motor carrier may transport passengers in a leased or interchanged commercial motor vehicle only under the following conditions:

(a) *In general*—(1) *Lease or agreement required.* There shall be in effect either:

(i) A lease granting the use of the passenger-carrying commercial motor vehicle and meeting the conditions of paragraphs (b) and (c) of this section. The provisions of the lease shall be adhered to and performed by the lessee; or

(ii) An agreement meeting the conditions of paragraphs (b) and (c) of this section and governing the interchange of passenger-carrying commercial motor vehicles between motor carriers of passengers conducting service on a route or series of routes. The provisions of the interchange agreement shall be adhered to and performed by the lessee.

(2) *Exception.* When an event occurs (*e.g.,* a crash, the vehicle is disabled) that requires a motor carrier of passengers immediately to obtain a replacement vehicle from another motor carrier of passengers, the two carriers may postpone the writing of the lease or written agreement for the replacement vehicle for up to 48 hours after the time the lessee takes exclusive possession and control of the replacement vehicle. However, during that 48-hour (or shorter) period, the driver of the vehicle must carry, and upon demand of an enforcement official produce, a document signed and dated by the lessee's driver or available company official stating: ''[Carrier A, USDOT number, telephone number] has leased this vehicle to [Carrier B, USDOT number, telephone number] pursuant to 49 CFR 390.403(a)(2).''

(b) *Contents of the lease.* The lease or interchange agreement required by paragraph (a) of this section shall contain:

(1) *Vehicle identification information.* The name of the vehicle manufacturer, the year of manufacture, and at least the last 6 digits of the Vehicle Identification Number (VIN) of each passenger-carrying commercial motor vehicle transferred between motor carriers pursuant to the lease or interchange agreement.

(2) *Parties.* The legal name, USDOT number, and telephone number of the motor carrier providing passenger transportation in a commercial motor vehicle (lessee) and the legal name, USDOT number, and telephone number of the motor carrier providing the equipment (lessor), and signatures of

both parties or their authorized representatives.

(3) *Specific duration.* The time and date when, and the location where, the lease or interchange agreement begins and ends.

(4) *Exclusive possession and responsibilities.* (i) A clear statement that the motor carrier obtaining the passenger-carrying commercial motor vehicle (the lessee) has exclusive possession, control, and use of the passenger-carrying commercial motor vehicle for the duration of the agreement, and assumes complete responsibility for operation of the vehicle and compliance with all applicable Federal regulations for the duration of the agreement.

(ii) In the event of a sublease between motor carriers, all of the requirements of this section shall apply to a sublease.

(c) *Copies of the lease.* A copy shall be on the passenger-carrying commercial motor vehicle during the period of the lease or interchange agreement, and both the lessee and lessor shall retain a copy of the lease or interchange agreement for 1 year after the expiration date.

Issued under the authority delegated in 49 CFR 1.87 on: September 11, 2018.

Raymond P. Martinez,

Administrator.

[FR Doc. 2018–20162 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–EX–P

FEDERAL REGISTER

Vol. 83 Thursday,
No. 183 September 20, 2018

Part IV

The President

Federal Register
Vol. 83, No. 183
Thursday, September 20, 2018

Presidential Documents

Title 3—

The President

Memorandum of August 23, 2018

Modernizing the Monetary Reimbursement Model for the Delivery of Goods Through the International Postal System and Enhancing the Security and Safety of International Mail

Memorandum for the Secretary of State[,] the Secretary of the Treasury[,] the Secretary of Homeland Security[,] the Postmaster General[, and] the Chairman of the Postal Regulatory Commission

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Definitions.* (a) ''Good'' means any tangible and movable object that can be conveyed by the international postal system, excluding (i) written, drawn, printed, or digital information recorded on a tangible medium that is not an object of merchandise and (ii) money.

(b) ''Non-postal operator'' means a private express carrier, freight forwarder, or other provider of services for the collection, transportation, and delivery of international documents and packages, other than a postal operator.

(c) ''Postal operator'' means a governmental or non-governmental entity officially designated by a Universal Postal Union (UPU) member country to operate postal services and to fulfill the related obligations arising out of the Acts of the UPU on its territory.

(d) ''Terminal dues'' means the rates or fees determined through the UPU and paid by the postal operator in the country of origin to the postal operator in the country of destination to compensate for costs incurred in the country of destination for processing, transportation, and delivery of international ''letter post'' items, which may include documents or goods and generally weigh up to 4.4 pounds.

Sec. 2. *Policy.* (a) The UPU was established in 1874 by 21 countries. The United States played an integral role in the UPU's creation and, since that time, the United States has actively participated in all phases of the UPU's work. The United States is a party to the current Constitution of the UPU—which was adopted in 1964—and intends to continue to participate fully in and financially contribute to the UPU, as provided in Article 21 of the UPU Constitution. As a member country of the UPU, the United States recognizes the importance of this long-standing organization and is proud of the United States' unbroken record of participation in it.

The Congress has provided that the Secretary of State (Secretary), in concluding postal treaties, conventions, or other international agreements, shall, to the maximum extent practicable, take measures to encourage governments of other countries to make available to the United States Postal Service (USPS) and private companies a range of nondiscriminatory customs procedures that will fully meet the needs of all types of American shippers (39 U.S.C. 407(e)(3)).

The Congress has likewise directed that responsible officials shall apply the customs laws of the United States and all other laws relating to importation or exportation of goods in the same manner to shipments of goods that are competitive products of the USPS and to similar shipments by private companies (39 U.S.C. 407(e)(2)).

It is the policy of the United States to promote and encourage the development of an efficient and competitive global system that provides for fair and nondiscriminatory postal rates.

(b) It is in the interest of the United States to:

(i) promote and encourage communications between peoples by efficient operation of international postal services and other international delivery services for cultural, social, and economic purposes (39 U.S.C. 407(a)(1));

(ii) promote and encourage unrestricted and undistorted competition in the provision of international postal services and other international delivery services, except where provision of such services by private companies may be prohibited by the laws of the United States (39 U.S.C. 407(a)(2));

(iii) promote and encourage a clear distinction between governmental and operational responsibilities with respect to the provision of international postal services and other international delivery services by the Government of the United States and by intergovernmental organizations of which the United States is a member (39 U.S.C. 407(a)(3)); and

(iv) participate in multilateral and bilateral agreements with other countries to accomplish these objectives (39 U.S.C. 407(a)(4)).

(c) Some current international postal practices in the UPU do not align with United States economic and national security interests:

(i) UPU terminal dues, in many cases, are less than comparable domestic postage rates. As a result:

(A) the United States, along with other member countries of the UPU, is in many cases not fully reimbursed by the foreign postal operator for the cost of delivering foreign-origin letter post items, which can result in substantial preferences for foreign mailers relative to domestic mailers;

(B) the current terminal dues rates undermine the goal of unrestricted and undistorted competition in cross-border delivery services because they disadvantage non-postal operators seeking to offer competing collection and outward transportation services for goods covered by terminal dues in foreign markets; and

(C) the current system of terminal dues distorts the flow of small packages around the world by incentivizing the shipping of goods from foreign countries that benefit from artificially low reimbursement rates.

(ii) The UPU has not done enough to reorient international mail to achieve a clear distinction between documents and goods. Without such a distinction, it is difficult to achieve essential pricing reforms or to ensure that customs requirements, including provision of electronic customs data for goods, are met. Under the current system, foreign postal operators do not uniformly furnish advance electronic customs data that are needed to enhance targeting and risk management for national security and to facilitate importation and customs clearance. My Administration's Initiative to Stop Opioids Abuse and Reduce Drug Supply and Demand, launched in March of this year, requires accurate advance electronic customs data for 90 percent of all international mail shipments that contain goods and consignment shipments within 3 years, so that the Department of Homeland Security can better detect and flag high-risk shipments.

(d) It shall be the policy of the executive branch to support efforts that further the policies in this memorandum, including supporting a system of unrestricted and undistorted competition between United States and foreign merchants. Such efforts include:

(i) ensuring that rates charged for delivery of foreign-origin mail containing goods do not favor foreign mailers over domestic mailers;

(ii) setting rates charged for delivery of foreign- origin mail in a manner that does not favor postal operators over non-postal operators; and

(iii) ensuring the collection of advance electronic customs data.

Sec. 3. *Relations with the UPU.* (a) The United States must seek reforms to the UPU that promote the policies outlined in this memorandum. Such reforms shall provide for:

(i) a system of fair and nondiscriminatory rates for goods that promotes unrestricted and undistorted competition; and

(ii) terminal dues rates that:

(A) fully reimburse the USPS for costs to the same extent as domestic rates for comparable services;

(B) avoid a preference for inbound foreign small packages containing goods that favors foreign mailers over domestic mailers; and

(C) avoid a preference for inbound foreign small packages containing goods that favors postal operators over private-sector entities providing transportation services.

(b) If negotiations at the UPU's September 2018 Second Extraordinary Congress in Ethiopia fail to yield reforms that satisfy the criteria set forth in subsection (a) of this section, the United States will consider taking any appropriate actions to ensure that rates for the delivery of inbound foreign packages satisfy those criteria, consistent with applicable law.

Sec. 4. *Actions by the Secretary.* (a) The Secretary shall notify the Director General of the UPU of the policies and intentions of the United States described in this memorandum.

(b) The Secretary or his designee shall, consistent with 39 U.S.C. 407(b)(1), seek agreement on future Convention texts that comport with the policies of this memorandum in meetings of the UPU, including at the September 2018 Extraordinary Congress.

(c) No later than November 1, 2018, the Secretary shall submit to the President a report summarizing the steps being taken to implement this memorandum. If the Secretary determines that sufficient progress on reforms to promote compatibility of the Acts of the UPU with the policy of this memorandum is not being achieved, the Secretary shall include recommendations for future action, including the possibility of adopting self-declared rates.

Sec. 5. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

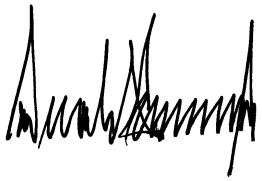
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum 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.

(d) The Secretary is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, August 23, 2018

[FR Doc. 2018–20667
Filed 9–19–18; 11:15 am]
Billing code 4710–10–P

Presidential Documents

Memorandum of August 31, 2018

Delegation of Authorities Under the Reinforcing Education Accountability in Development Act

Memorandum for the Secretary of State [and] the Administrator of the United States Agency for International Development

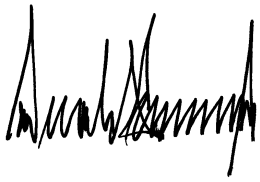
By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby:

(1) delegate to the Secretary of State the functions and authorities vested in the President by sections 4, 6, and 7 of the Reinforcing Education Accountability in Development (READ) Act, (Div. A, Public Law 115–56); and

(2) delegate to the Administrator of the United States Agency for International Development the functions and authorities vested in the President by section 5(c) of the READ Act.

The delegations in this memorandum shall apply to any provisions of any future public laws that are the same or substantially the same as the provisions referenced in this memorandum. The Secretary of State or the Administrator of the United States Agency for International Development, as appropriate, may redelegate the functions delegated by this memorandum to the extent authorized by law.

The Secretary of State is authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, August 31, 2018

[FR Doc. 2018–20668
Filed 9–19–18; 11:15 am]
Billing code 4710–10–P

FEDERAL REGISTER

Vol. 83 Thursday,
No. 183 September 20, 2018

Part V

The President

Notice of September 19, 2018—Continuation of the National Emergency With Respect to Persons Who Commit, Threaten To Commit, or Support Terrorism

Federal Register
Vol. 83, No. 183
Thursday, September 20, 2018

Presidential Documents

Title 3—

The President

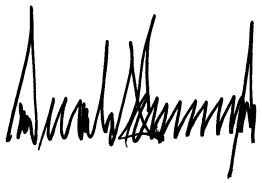
Notice of September 19, 2018

Continuation of the National Emergency With Respect to Persons Who Commit, Threaten To Commit, or Support Terrorism

On September 23, 2001, by Executive Order 13224, the President declared a national emergency with respect to persons who commit, threaten to commit, or support terrorism, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the terrorist attacks on September 11, 2001, in New York and Pennsylvania and against the Pentagon, and the continuing and immediate threat of further attacks against United States nationals or the United States.

The actions of persons who commit, threaten to commit, or support terrorism continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 13224 of September 23, 2001, and the measures adopted on that date to deal with that emergency, must continue in effect beyond September 23, 2018. 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 with respect to persons who commit, threaten to commit, or support terrorism declared in Executive Order 13224.

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



THE WHITE HOUSE,
September 19, 2018.

[FR Doc. 2018–20703
Filed 9–19–18; 2:00 pm]
Billing code 3295–F8–P

Reader Aids

Federal Register

Vol. 83, No. 183

Thursday, September 20, 2018

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

44815–45030 4
45031–45192 5
45193–45324 6
45325–45534 7
45535–45810 10
45811–46066 11
46067–46348 12
46349–46626 13
46627–46848 14
46849–47026 17
47027–47282 18
47283–47546 19
47547–47800 20

CFR PARTS AFFECTED DURING SEPTEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
9704 45019
9705 45025
9710 45019
9711 45025
9739 45019
9740 45025
9776 45019
9777 45025
9778 45313
9779 45315
9780 45317
9781 46345
9782 46625
9783 47279
9784 47281
9785 47539
9786 47541
9787 47543
9788 47545
Executive Orders:
13847 45321
13848 46843
Adminstrative Orders:
Memorandums:
Memorandum of August 23, 2018 47791
Memorandum of August 31, 2018 47795
Presidential Determination No. 2018–11 of September 10, 2018 46347
Notices:
Notice of August 31, 2018 45191
Notice of September 10, 2018 46067
Notice of September 19, 2018 47799

5 CFR

Ch. XIV 46349
1653 47547

7 CFR

318 46627
319 46627
457 45535
929 46069
1709 45031
1739 45031
1776 45031
1783 45031
Proposed Rules:
301 47310
927 46119
929 46661
3201 46780

8 CFR

Proposed Rules:
212 45486
236 45486

9 CFR

Proposed Rules:
557 ..... 47524, 47528, 47532

10 CFR

Proposed Rules:
Ch. I 45359
430 46886
431 ..... 45052, 45851, 46886

11 CFR

Proposed Rules:
113 46888

12 CFR

229 46849
1003 45325
1022 47027
1070 46075
Proposed Rules:
25 45053
30 47313
44 45860
101 47101
195 45053
248 45860
351 45860
Ch. X 45574
1248 46889

14 CFR

25 ..... 45034, 45037, 46098, 46101, 47548
39 ..... 44815, 45037, 45041, 45044, 45333, 45335, 45539, 45545, 45548, 45550, 45811, 46369, 46372, 46374, 46377, 46380, 46384, 46853, 46857, 46859, 46862, 47042, 47044, 47047, 47054, 47056
71 ..... 45337, 45554, 45813, 45814, 45815, 45816, 45818, 45819, 45820, 46386, 46387, 46389, 46390, 46391, 46639, 46864
91 47059
93 ..... 46865, 47065
97 ..... 44816, 44819, 45822, 45824
295 46867
298 46867
Proposed Rules:
39 ..... 44844, 45359, 45362, 45364, 45578, 45580, 46424, 46426, 46428, 46664, 46666, 46670, 46677, 46679, 46895, 46898, 46900, 46902, 46905,

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

H.R. 5385/P.L. 115–241
Dr. Benjy Frances Brooks Children's Hospital GME Support Reauthorization Act of 2018 (Sept. 18, 2018; 132 Stat. 2892)

H.R. 5772/P.L. 115–242
To designate the J. Marvin Jones Federal Building and Courthouse in Amarillo, Texas, as the ''J. Marvin Jones Federal Building and Mary Lou Robinson United States Courthouse''. (Sept. 18, 2018; 132 Stat. 2893)

Last List September 19, 2018

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.