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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2016–0137]

RIN 3150–AJ77

List of Approved Spent Fuel Storage Casks: NAC International MAGNASTOR® Cask System; Certificate of Compliance No. 1031, Amendment No. 6

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of December 21, 2016, for the direct final rule that was published in the **Federal Register** on October 7, 2016. The direct final rule amended the NRC's spent fuel storage regulations by revising the ''List of approved spent fuel storage casks'' to include Amendment No. 6 to Certificate of Compliance (CoC) No. 1031 for the NAC International, MAGNASTOR® Cask System.

DATES: *Effective Date:* The effective date of December 21, 2016, for the direct final rule published October 7, 2016 (81 FR 69659), is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2016–0137 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 Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0137. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- 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 ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** 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, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Keith McDaniel, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5252; email: *Keith.McDaniel@nrc.gov.*

SUPPLEMENTARY INFORMATION: On October 7, 2016 (81 FR 69659), the NRC published a direct final rule amending § 72.214 of title 10 of the *Code of Federal Regulations* by revising the ''List of approved spent fuel storage casks'' to include Amendment No. 6 to CoC No. 1031 for the NAC International, MAGNASTOR® Cask System. Amendment No. 6 revises NAC MAGNASTOR technical specifications (TSs) to align with the NAC Multi-Purpose Canister (MPC) and NAC Universal MPC System TSs. The CoC No. 1031 TSs require that a program be established and maintained for loading, unloading, and preparing fuel for storage without any indication of duration for the program. Amendment No. 6 limits maintenance of this program until all spent fuel is removed from the spent fuel pool and transport operations are completed. Related training and radiation protection program requirements are modified accordingly. Additionally, Amendment No. 6 incorporates the change to Limiting Condition for Operation 3.1.1 previously approved by the NRC in CoC No. 1031, Amendment No. 4.

In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on December 21, 2016. As described more fully in the direct final rule, a significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change.

The NRC received one comment on the direct final rule (ADAMS Accession No. ML16300A435). The comment stated ''While the casks themselves are obviously important, nobody wants depleted uranium from leaking, the real problem is the long term effects of not finding proper storage for our spent nuclear fuel. Nuclear power is the power of the future, and yet we have no definitive solution as to where to store this stuff in bulk.'' The NRC determined that this general comment about spent fuel storage is not within the scope of the direct final rule, which is limited to the specific changes contained in Amendment No. 6 to CoC No. 1031. The NRC also determined that this was not a significant adverse comment and did not make any changes to the direct final rule as a result of the public comment. Therefore, because no significant adverse comments were received, the direct final rule will become effective as scheduled. The final CoC, TSs, and Safety Evaluation Report can be viewed in ADAMS under Accession No. ML16319A064.

Dated at Rockville, Maryland, this 1rst day of December, 2016.

For the Nuclear Regulatory Commission.

Cindy Bladey,

Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2016–29275 Filed 12–6–16; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 431

[Docket No. EERE–2014–BT–TP–0006]

RIN 1904–AD16

Energy Conservation Program: Test Procedure for Commercial Packaged Boilers; Withdrawal

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

ACTION: Final rule; withdrawal.

SUMMARY: The U.S. Department of Energy (DOE) is withdrawing its final rule to amend its test procedure for commercial packaged boilers which published in the **Federal Register** on Thursday, November 10, 2016. The final rule published on November 10, 2016 contained errors. Therefore, DOE is withdrawing the final rule in its entirety and will republish the final rule amending its test procedure for commercial packaged boilers.

DATES: Effective December 7, 2016, the final rule published November 10, 2016 (81 FR 79224), effective December 12, 2016, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Mr. James Raba, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–8654. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE is withdrawing its final rule to amend its test procedure for commercial packaged boilers which published in the **Federal Register** on Thursday, November 10, 2016 (81 FR 79224). Among other amendments, the final rule incorporates by reference certain sections of the American National Standards Institute (ANSI)/Air-Conditioning, Heating, and Refrigeration Institute (AHRI) Standard 1500, ''2015 Standard for Performance Rating of Commercial Space Heating Boilers,'' provides an optional field test for commercial packaged boilers with rated input greater than 5,000,000 Btu/h, and modifies the inlet water temperatures during tests of hot water commercial packaged boilers.

Because the November 10, 2016, rule contained errors, DOE is withdrawing the final rule in its entirety and will republish the final rule amending its test procedure for commercial packaged boilers.

Issued in Washington, DC, on November 29, 2016.

Kathleen B. Hogan,

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

[FR Doc. 2016–29078 Filed 12–6–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2016–9461; Special Conditions No. 25–642–SC]

Special Conditions: Embraer S.A., Model ERJ 190–300 Series Airplanes; Landing Pitchover Condition

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Embraer S.A. Model ERJ 190–300 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is an automatic braking system with a pilot-selectable function that allows earlier braking at landing without pilot pedal input. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Embraer S.A. on December 7, 2016. We must receive your comments by January 23, 2017.

ADDRESSES: Send comments identified by docket number FAA–2016–9461 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/*and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

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

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

FOR FURTHER INFORMATION CONTACT: Greg Schneider, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–2116; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would delay issuance of the design approval and thus delivery of the affected airplane.

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

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

We will consider all comments we receive by the closing date for

comments. We may change these special conditions based on the comments we receive.

Background

On September 13, 2013, Embraer S.A. applied for an amendment to Type Certificate (TC) No. A57NM to include the new Model ERJ 190–300 series airplanes. The ERJ 190–300, which is a derivative of the ERJ 190–100 STD currently approved under TC No. A57NM, is a 97–114 passenger transport category airplane with two Pratt & Whitney Model PW1900G engines, a new wing design with a high aspect ratio and raked wingtip, digital fly-by-wire electronic flight control system, and an automatic braking system.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.101, Embraer S.A. must show that the ERJ 190–300 meets the applicable provisions of the regulations listed in Type Certificate No. A57NM or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA. Embraer S.A. must show that the ERJ 190–300 meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–137.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the ERJ 190–300 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the Model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design features, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the ERJ 190–300 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The ERJ 190–300 will incorporate the following novel or unusual design features:

An automatic braking system with a pilot-selectable function that allows earlier braking at landing without pilot pedal input. When the autobrake system is armed before landing, it automatically commands a pre-defined braking action after the main wheels touch down. This might cause a high nose gear sink rate, and potentially higher gear and airframe loads than would occur with a traditional braking system.

Discussion

These special conditions define a landing pitchover condition that accounts for the effects of the automatic braking system. The special conditions define the airplane configuration, speeds, and other parameters necessary to develop airframe and nose gear loads for this condition. The special conditions require that the airplane be designed to support the resulting limit and ultimate loads as defined in § 25.305.

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

Applicability

As discussed above, these special conditions are applicable to the ERJ 190–300 series airplanes. Should Embraer S.A. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Embraer S.A. Model ERJ 190–300 series airplanes.

A landing pitchover condition must be addressed that takes into account the effect of the autobrake system. The airplane is assumed to be at the design maximum landing weight, or at the maximum weight allowed with the autobrake system on. The airplane is assumed to land in a tail-down attitude and at the speeds defined in § 25.481. Following main gear contact, the airplane is assumed to rotate about the main gear wheels at the highest pitch rate allowed by the autobrake system.

This is considered a limit load condition from which ultimate loads must also be determined. Loads must be determined for critical fuel and payload distributions and centers of gravity. The effect of the autobrake system on fatigue loading spectra must also be investigated. Nose gear loads, as well as airframe loads, must be determined. The airplane must meet § 25.305 for these loads.

Issued in Renton, Washington, on November 15, 2016.

Paul Bernado,

Acting Manager, Transport Airplane Directorate Aircraft Certification Service.

[FR Doc. 2016–29358 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0146]

Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry and FDA staff entitled ''Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards.'' The guidance contains FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by the FDA Food Safety Modernization Act (FSMA). The guidance is intended to describe the standards for accreditation of third-party certification bodies as required under the final rule entitled ''Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.'' In addition, this guidance discusses specific clauses of ISO/IEC 17021: 2015 and industry practice that are currently being used by third-party certification bodies and that FDA recommends accreditation bodies consider as a model when making accreditation decisions.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2011–N–0146 for ''Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Charlotte A. Christin, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7526.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry and FDA staff entitled ''Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. 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.

In the **Federal Register** of July 24, 2015 (80 FR 44137), we made available a draft guidance entitled ''Draft Guidance for Industry and Food and Drug Administration Staff: Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards'' and gave interested parties an opportunity to submit comments by October 7, 2015, for us to consider before beginning work on the final version of the guidance. Section 808 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 384d) was added by FSMA and directs FDA to establish a program for the recognition of accreditation bodies that accredit third-party certification bodies to conduct food safety audits and to issue food and/or facility certifications that FDA may use in certain circumstances to facilitate the entry of foods presented for import.

Section 808(b)(2) of the FD&C Act requires FDA to develop model accreditation standards that recognized accreditation bodies shall use to qualify third-party certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs. This guidance constitutes the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. The guidance contains FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by FSMA.

FDA was guided in developing this guidance, in part, by the National Technology Transfer and Advancement Act of 1995, which directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical.

In developing the guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party certification bodies that would certify foreign food facilities and/or their foods for conformance with the requirements of the FD&C Act. FDA also sought to identify the standards most commonly used by stakeholders (*e.g.,* other governments, public and private accreditation bodies, the food industry, and the international standards community) in qualifying third-party certification bodies for conducting food safety audits. As a result, FDA was guided in developing the model accreditation standards guidance document by International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) ISO/IEC 17021: *Conformity Assessment—Requirements for bodies providing audit and certification management systems* (2015) (ISO/IEC 17021:2015) and ISO/IEC 17065: *Conformity Assessment—Requirements for bodies certifying products, processes and services* (2012) (ISO/IEC 17065:2012).

We received several comments on the draft guidance and have modified the final guidance where appropriate. We revised the guidance for clarity and conformance with the final rule. We also updated references to the ISO/IEC standards. The guidance announced in this notice finalizes the draft guidance dated July 2015.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collection of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding ''Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications,'' have been approved under OMB control number 0910–0750.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29278 Filed 12–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 41

RIN 1400–AD96

[Public Notice: 9638]

Visas: Classification of Immediate Family Members as A, C–3, G, and NATO Nonimmigrants

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: This rule amends the definition of immediate family for purposes of A, C–3, G, and NATO visa classifications in two ways: It revises the eligibility requirements for unmarried adult sons and daughters age 21 or older for these visa classifications, and clarifies for purposes of G–4 visa classification that the international organization employing the principal alien must recognize an individual as immediate family to be eligible for derivative U.S. visa status. Furthermore, this rule permits qualified immediate family members of A–1, A–2, G–1, G–2, G–3, and G–4 nonimmigrants to be independently classified as NATO–1, NATO–2, NATO–3, NATO–4, NATO–5, and NATO–6.

DATES: This final rule is effective on December 7, 2016.

FOR FURTHER INFORMATION CONTACT: Paul-Anthony L. Magadia, U.S. Department of State, Office of Legislation and Regulations, CA/VO/L/R, 600 19th Street NW., SA–17, Room 12–526B, Washington, DC 20522, 202–485–7641 or *magadiapl@state.gov.*

SUPPLEMENTARY INFORMATION: Prior to this amendment, an unmarried adult son or daughter who is not part of any other household and resides regularly in the household of the principal alien must be classified in A or G visa classifications, even if otherwise eligible for another nonimmigrant classification and regardless of age or the intention of the sending government or international organization. Yet for purposes of privileges and immunities, the Department of State accepts only unmarried children under the age of 21, or unmarried sons and daughters under the age of 23 and in full-time attendance as students at post-secondary educational institutions, as dependents. Similarly, under 8 CFR 214.2(a)(2) and (g)(2) for employment authorization purposes, Department of Homeland Security (DHS) regulations generally only consider unmarried children under the age of 21, or unmarried sons and daughters under the age of 23 and in full-time attendance as students at post-secondary educational institutions, to be dependents. (Under certain circumstances, DHS, under its regulations, may also recognize as dependents sons and daughters up to the age of 25 or of any age if physically or mentally challenged.) In practice, requiring A or G classification for sons and daughters above these age limits precludes them from obtaining a nonimmigrant classification that would enable them to accept employment in the United States.

This rule narrows the definition of immediate family in the A, C–3 (aliens in transit under section 212(d)(8) of the Immigration and Nationality Act, 8 U.S.C. 1182(d)(8)), G, and relevant NATO nonimmigrant visa classifications so that only unmarried sons and daughters residing with the principal who are under the age of 21, or under the age of 23 and in full-time attendance as students at post-secondary educational institutions, will continue to be considered immediate family. Any other unmarried son or daughter residing with the principal will only qualify if he or she meets the same criteria the rule imposes on other family members. In particular, he or she must be recognized as an ''immediate family member'' by the sending government or international organization for purposes of eligibility for rights and benefits and also is individually authorized by the Department. An adult son or daughter

who is no longer recognized as an immediate family member would have to apply, and be eligible for, another visa classification or seek a change of status to another nonimmigrant status. This rule also amends 22 CFR 41.21(a)(3)(iii)(C) to clarify that for purposes of G–4 visa classification, the employing international organization must recognize individuals as immediate family members, before they may be treated as such for U.S. visa purposes, similar to the requirement that a sending government must recognize an individual as immediate family.

Finally, prior to this amendment, 22 CFR 41.22(b) and 41.24(b) required that an alien entitled to classification as an A–1, A–2, or G–1 through G–4 nonimmigrant must be classified as such, even those who would otherwise be eligible for another nonimmigrant classification. This rule allows immediate family members of A–1s, A–2s, and G–1s through G–4s to be instead independently classified as a principal in NATO–1 through NATO–6 visa classifications, but not other nonimmigrant classifications.

Regulatory Findings

Administrative Procedure Act

The Department of State is of the opinion that regulating visa categories involves a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. Since the Department is of the opinion that this rule is exempt from 5 U.S.C. 553, it is the view of the Department that the provisions of Section 553(d) do not apply. Therefore, this rule is effective upon publication.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory Flexibility Act (5 U.S.C. 603 and 604). Nonetheless, consistent with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule does not require the Department to prepare a statement because it will not result in any such expenditure, nor will it significantly or uniquely affect small governments. This rule involves visas, which involves individuals, and does not affect, state, local, or tribal governments, or businesses.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined in 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets. This rule involves visas, which involves individuals, and does not affect, state, local, or tribal governments, or businesses.

Executive Orders 12866 and 13563

Executive Orders 13563 and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). These Executive Orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Department has examined this rule in light of Executive Order 13563, and has determined that the rulemaking is consistent with the guidance therein.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders 12372 and 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the rule in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Section 5 of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose or revise any reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 41

Aliens, Immigration, Nonimmigrant visas.

For the reasons stated in the preamble, 22 CFR part 41 is amended as follows:

PART 41—[AMENDED]

■ 1. The authority citation for part 41 continues to read as follows:

Authority: 22 U.S.C. 2651a; 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681–795 through 2681–801; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458, as amended by section 546 of Pub. L. 109–295).

■ 2. Section 41.21 is amended by revising paragraph (a)(3) to read as follows:

§ 41.21 Foreign Officials—General.

(a) * * *

(3) Immediate family, as used in INA 101(a)(15)(A), 101(a)(15)(G), and 212(d)(8), and in classification under the NATO visa symbols, means:

(i) The spouse who resides regularly in the household of the principal alien and is not a member of some other household;

(ii) Unmarried sons and daughters, whether by blood or adoption, who reside regularly in the household of the principal alien and who are not members of some other household, and provided that such unmarried sons and daughters are:

(A) Under the age of 21, or

(B) Under the age of 23 and in full-time attendance as students at post-secondary educational institutions; and

(iii) Other individuals who:

(A) Reside regularly in the household of the principal alien;

(B) Are not members of some other household;

(C) Are recognized as dependents of the principal alien by the sending government or international organization, as demonstrated by eligibility for rights and benefits, such as the issuance of a diplomatic or official passport, or travel or other allowances; and

(D) Are individually authorized by the Department.

* * * * *

■ 3. Section 41.22 is amended by revising paragraph (b) to read as follows:

§ 41.22 Officials of foreign governments.

* * * * *

(b) *Classification under INA section 101(a)(15)(A).* An alien entitled to classification under INA section 101(a)(15)(A) shall be classified under this section even if eligible for another nonimmigrant classification. An exception may be made where an immediate family member is classifiable as A–1 or A–2 under paragraph (a)(2) of this section is also independently classifiable as a principal under INA section 101(a)(15)(G)(i), (ii), (iii), (iv) or in NATO–1 through NATO–6 classification.

* * * * *

■ 4. Section 41.24 is amended by revising paragraph (b)(4) to read as follows:

§ 41.24 International organization aliens.

* * * * *

(b) * * *

(4) An alien not classifiable under INA section 101(a)(15)(A) or in NATO–1 through NATO–6 classification but entitled to classification under INA section 101(a)(15)(G) shall be classified under section 101(a)(15)(G), even if also eligible for another nonimmigrant classification. An alien classified under INA section 101(a)(15)(G) as an immediate family member of a principal alien classifiable G–1, G–2, G–3 or G–4, may continue to be so classified even if he or she obtains employment subsequent to his or her initial entry into the United States that would allow classification under INA section 101(a)(15)(A). Such alien shall not be classified in a category other than A or G, even if also eligible for another nonimmigrant classification.

* * * * *

Michele Thoren Bond,

Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. 2016–28518 Filed 12–6–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9800]

RIN 1545–BM75

Covered Asset Acquisitions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary Income Tax Regulations under section 901(m) of the Internal Revenue Code (Code) with respect to transactions that generally are treated as asset acquisitions for U.S. income tax purposes and either are treated as stock acquisitions or are disregarded for foreign income tax purposes. These regulations are necessary to provide guidance on applying section 901(m). The text of the temporary regulations also serves in part as the text of the proposed regulations under section 901(m) (REG–129128–14) published in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective date:* These regulations are effective on December 7, 2016.

Applicability dates: For dates of applicability, see §§ 1.901(m)–1T(b), 1.901(m)–2T(f), 1.901(m)–4T(g), 1.901(m)–5T(i), and 1.901(m)–6T(d).

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Parry, (202) 317–6936 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

I. Section 901(m)

Section 212 of the Education Jobs and Medicaid Assistance Act (EJMAA), enacted on August 10, 2010 (Public Law 111–226), added section 901(m) to the Code. Section 901(m)(1) provides that, in the case of a covered asset acquisition (CAA), the disqualified portion of any foreign income tax determined with respect to the income or gain attributable to relevant foreign assets (RFAs) will not be taken into account in determining the foreign tax credit allowed under section 901(a), and in the case of foreign income tax paid by a section 902 corporation (as defined in section 909(d)(5)), will not be taken into account for purposes of section 902 or 960. Instead, the disqualified portion of any foreign income tax (the disqualified tax amount) is permitted as a deduction. See section 901(m)(6).

Under section 901(m)(2), a CAA is (i) a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies; (ii) any transaction that is treated as an acquisition of assets for U.S. income tax purposes and as the acquisition of stock of a corporation (or is disregarded) for purposes of a foreign income tax; (iii) any acquisition of an interest in a partnership that has an election in effect under section 754; and (iv) to the extent provided by the Secretary, any other similar transaction.

Section 901(m)(3)(A) provides that the term ''disqualified portion'' means, with respect to any CAA, for any taxable year, the ratio (expressed as a percentage) of (i) the aggregate basis differences (but not below zero) allocable to such taxable year with respect to all RFAs; divided by (ii) the income on which the foreign income tax referenced in section 901(m)(1) is determined. If the taxpayer fails to substantiate the income on which the foreign income tax is determined to the satisfaction of the Secretary, such income will be determined by dividing the amount of such foreign income tax by the highest marginal tax rate applicable to the taxpayer's income in the relevant jurisdiction.

Section 901(m)(3)(B)(i) provides the general rule that the basis difference with respect to any RFA will be allocated to taxable years using the applicable cost recovery method for U.S. income tax purposes. Section 901(m)(3)(B)(ii) provides that, except as otherwise provided by the Secretary, if there is a disposition of an RFA, the basis difference allocated to the taxable year of the disposition will be the excess of the basis difference of such asset over the aggregate basis difference of such asset that has been allocated to all prior taxable years. The statute further provides that no basis difference with respect to such asset will be allocated to any taxable year thereafter.

Section 901(m)(3)(C)(i) provides that basis difference means, with respect to any RFA, the excess of (i) the adjusted basis of such asset immediately after the CAA, over (ii) the adjusted basis of such asset immediately before the CAA. If the adjusted basis of an RFA immediately before the CAA exceeds the adjusted basis of the RFA immediately after the CAA (that is, where the adjusted basis

of an asset with a built-in loss is reduced in a CAA), such excess is taken into account as a basis difference of a negative amount. See section 901(m)(3)(C)(ii).

Section 901(m)(4) provides that an RFA means, with respect to a CAA, an asset (including goodwill, going concern value, or other intangible) with respect to such acquisition if income, deduction, gain, or loss attributable to such asset is taken into account in determining the foreign income tax referenced in section 901(m)(1).

Section 901(m)(7) provides that the Secretary may issue regulations or other guidance as is necessary or appropriate to carry out the purposes of section 901(m).

II. Notices 2014–44 and 2014–45

The Department of the Treasury (Treasury Department) and the IRS issued Notice 2014–44 (2014–32 I.R.B 270 (July 21, 2014)) and Notice 2014–45 (2014–34 I.R.B. 388 (July 29, 2014)), announcing the intent to issue regulations addressing the application of section 901(m) to dispositions of RFAs following CAAs and to CAAs described in section 901(m)(2)(C) (regarding section 754 elections).

The notices were issued in response to certain taxpayers engaging in transactions shortly after a CAA with the intention of invoking the application of the statutory disposition rule under section 901(m)(3)(B)(ii) to avoid the purposes of section 901(m). To address these transactions, Notice 2014–44 described the definition of disposition that would be set forth in future regulations, as well as the rules for determining the portion of basis difference that would be taken into account upon a disposition of an RFA (the disposition amount). In addition, Notice 2014–44 described the computation of basis difference and disposition amount with respect to an RFA that is subject to a section 743(b) CAA. Notice 2014–44 also announced that future regulations would provide successor rules for the continued application of section 901(m) after a subsequent transfer of an RFA with remaining basis difference. Notice 2014–44 further provided that future regulations would provide that, if an asset is an RFA with respect to two section 743(b) CAAs involving the same partnership interest, the RFA will be treated as having no remaining basis difference with respect to the first section 743(b) CAA if the basis difference with respect to the second section 743(b) CAA is determined independently from the first section 743(b) CAA. In this regard, see generally § 1.743–1(f) and proposed § 1.743–1(f)(2).

Notice 2014–44 provided that the future regulations described therein would apply (i) concerning dispositions, to dispositions occurring on or after July 21, 2014 (the date Notice 2014–44 was issued), (ii) concerning section 743(b) CAAs, to section 743(b) CAAs occurring on or after July 21, 2014, unless a taxpayer consistently applied those provisions to all section 743(b) CAAs occurring on or after January 1, 2011, and (iii) concerning successor rules, to remaining basis difference with respect to an RFA as of July 21, 2014, and any basis difference with respect to an RFA that arises in a CAA occurring on or after July 21, 2014. Notice 2014–45 provided that the future regulations described in Notice 2014–44 also would apply to determine the tax consequences under section 901(m) of an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014 (the date Notice 2014–45 was issued), including whether a disposition results from the election for purposes of section 901(m) and the treatment of any remaining basis difference that results from such an election.

III. Proposed Regulations Under Section 901(m)

Proposed regulations under section 901(m) are being issued at the same time as these temporary regulations. In addition to cross-referencing these temporary regulations, the proposed regulations provide guidance under section 901(m) concerning issues not addressed in the temporary regulations. Consulting the preamble to the proposed regulations is recommended for a better understanding of how these temporary regulations are intended to work.

Explanation of Provisions

I. Overview

Section 1.901(m)–1T provides definitions that apply for purposes of the temporary regulations. Section 1.901(m)–2T identifies the transactions that are CAAs and the assets that are RFAs with respect to a CAA. Section 1.901(m)–4T provides the general rule for determining basis difference with respect to an RFA under section 901(m)(3)(C), as well as a special rule for determining basis difference with respect to an RFA that arises as a result of an acquisition of an interest in a partnership that has made a section 754 election (section 743(b) CAA). Section 1.901(m)–5T provides rules for taking into account basis difference under the applicable cost recovery method or as a result of a disposition of an RFA. Section 1.901(m)–6T provides successor rules for applying section 901(m) to subsequent transfers of RFAs that have basis difference that has not yet been fully taken into account.

II. Effective/Applicability Dates

The applicability dates of the temporary regulations relate back to the issuance of Notices 2014–44 and 2014–45. Accordingly, the temporary regulations apply to CAAs occurring on or after July 21, 2014, and to CAAs occurring before that date resulting from an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014 (referred to as the general applicability date). The temporary regulations also apply to CAAs occurring on or after January 1, 2011, and before the general applicability date (the transition period), but only if the basis difference within the meaning of section 901(m)(3)(C)(i) (statutory basis difference) in one or more RFAs with respect to such a CAA had not been fully taken into account under section 901(m)(3)(B) either as of July 21, 2014, or, in the case of an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, prior to the transactions that are deemed to occur under § 301.7701–3(g) as a result of the change in classification.

Taxpayers also may choose to consistently apply § 1.901(m)–4T(d)(1) (regarding the determination of basis difference in an RFA with respect to a section 743(b) CAA) to all section 743(b) CAAs occurring on or after January 1, 2011.

III. CAAs and RFAs

Section 1.901(m)–2T(b) identifies the transactions that are CAAs under section 901(m)(2)(A) through (C). Section 1.901(m)–2T(c) provides that, with respect to a foreign income tax and a CAA, an RFA is any asset (including goodwill, going concern value, or other intangible) subject to the CAA that is relevant in determining foreign income for purposes of the foreign income tax. An asset is subject to a CAA, if, for example (i) in the case of a qualified stock purchase of a target corporation (as defined in section 338(d)(3)) to which section 338(a) applies, ''new'' target is treated as purchasing the asset from ''old'' target; (ii) in the case of a taxable acquisition of a disregarded entity that is treated as an acquisition of stock for foreign income tax purposes,

the asset is owned by the disregard entity at that time of the purchase and therefore the buyer is treated as purchasing the asset from the seller; and (iii) in the case of a section 743(b) CAA, the asset is attributable to the partnership interest transferred in the section 743(b) CAA.

Section 1.901(m)–2T(d) provides that the statutory definitions under section 901(m)(2) and 901(m)(4) apply to determine whether a transaction that occurred during the transition period is a CAA and which assets are RFAs with respect to those CAAs, respectively.

IV. Determining Basis Difference With Respect to an RFA

A basis difference is computed separately with respect to each foreign income tax for which an asset is an RFA. Consistent with section 901(m)(3)(C), § 1.901(m)–4T(b) provides the general rule that basis difference with respect to an RFA is the U.S. basis in the RFA immediately after the CAA, less the U.S. basis in the RFA immediately before the CAA. If, however, an asset is an RFA with respect to a section 743(b) CAA, § 1.901(m)–4T(d) provides that basis difference with respect to the RFA is the resulting basis adjustment under section 743(b) that is allocated to the RFA under section 755.

Section 1.901(m)–2T(e) ''resets'' the basis difference in an RFA with respect to a CAA that occurred during the transition period by defining basis difference in the RFA as the portion of statutory basis difference that had not been taken into account under section 901(m)(3)(B) either as of July 21, 2014, or, in the case of an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, prior to the transactions that are deemed to occur under § 301.7701–3(g) as a result of the change in classification. This is the basis difference in the RFA for the period to which the temporary regulations apply.

V. Basis Difference Taken Into Account

Section 1.901(m)–5T provides rules for determining the amount of basis difference with respect to an RFA that is taken into account in a given U.S. taxable year (allocated basis difference). The amount of basis difference taken into account in a U.S. taxable year is used to compute a disqualified tax amount for the U.S. taxable year. Basis difference is taken into account in two ways: Under an applicable cost recovery method or as a result of a disposition of the RFA. If an asset is an RFA with respect to more than one foreign income tax, basis difference with respect to each foreign income tax is separately taken into account under § 1.901(m)–5T.

A. Determining Cost Recovery Amounts

Consistent with section 901(m)(3)(B)(i), § 1.901(m)–5T(b)(2) provides that a cost recovery amount for an RFA is determined by applying an applicable cost recovery method to the basis difference rather than to the U.S. basis of the RFA.

B. Determining Disposition Amounts

1. Overview

Section 901(m)(3)(B)(ii) provides that, except as otherwise provided by the Secretary, if there is a disposition of an RFA, the basis difference allocated to the U.S. taxable year of the disposition shall be the excess of the basis difference of such RFA over the total amount of such basis difference that has been allocated to all prior U.S. taxable years (unallocated basis difference). This result is appropriate when all the gain or loss from the disposition is recognized for both U.S. and foreign income tax purposes. In other cases, however, a disposition may not be the appropriate time for all of the unallocated basis difference to be taken into account. For example, it may not be appropriate for all of the unallocated basis difference to be taken into account upon a disposition that is fully taxable for U.S. income tax purposes but not for foreign income tax purposes. Accordingly, under the specific authority granted to the Secretary with respect to dispositions, these temporary regulations provide rules to determine when less than all of the unallocated basis difference is taken into account as a result of a disposition.

2. Definition of Disposition

Section 1.901(m)–1T(a)(10) defines a disposition for purposes of section 901(m) as an event that results in gain or loss being recognized with respect to an RFA for purposes of U.S. income tax or foreign income tax, or both. Thus, the definition excludes certain transfers that might otherwise be considered dispositions under the ordinary meaning of that term. For example, an entity classification election by an RFA owner that results in a tax-free deemed liquidation for U.S. income tax purposes but that is disregarded for foreign income tax purposes does not result in a disposition of the RFAs under section 901(m), because no gain or loss is recognized for U.S. or foreign income tax purposes with respect to the distribution of the RFAs in the deemed liquidation. This is the case even though the deemed liquidation might otherwise be considered a ''disposition'' of assets under other provisions of the Code.

3. Determining a Disposition Amount

Section 1.901(m)–5T(c)(2) provides rules for determining a disposition amount. If a disposition of an RFA is fully taxable for U.S. and foreign income tax purposes, the disposition amount will be any remaining unallocated basis difference with respect to that RFA. This is because there generally will no longer be a disparity in the U.S. basis and the foreign basis of the RFA.

If a disposition is not fully taxable for both U.S. and foreign income tax purposes, generally there will continue to be a disparity in the U.S. basis and the foreign basis following the disposition, and it will be appropriate for the RFA to continue to have unallocated basis difference. To the extent that the disparity in the U.S. basis and the foreign basis is reduced as a result of the disposition, however, a portion of the unallocated basis difference (or, in certain cases, all of the unallocated basis difference) should be taken into account. Whether the disposition reduces the basis disparity will depend on whether the basis difference is positive or negative and the jurisdiction in which gain or loss is recognized.

If an RFA has a positive basis difference, a reduction in basis disparity generally will occur upon a disposition of the RFA if (i) a foreign disposition gain is recognized, which generally results in an increase in the foreign basis of the RFA, or (ii) a U.S. disposition loss is recognized, which generally results in a decrease in the U.S. basis of the RFA. Accordingly, if an RFA has a positive basis difference, the disposition amount equals the lesser of (i) any foreign disposition gain plus any U.S. disposition loss (for this purpose, expressed as a positive amount), or (ii) unallocated basis difference. See § 1.901(m)–5T(c)(2)(ii)(A).

If an RFA has a negative basis difference, a reduction in basis disparity generally will occur upon a disposition of the RFA if (i) a foreign disposition loss is recognized, which generally results in a decrease in the foreign basis of the RFA, or (ii) a U.S. disposition gain is recognized, which generally results in an increase in the U.S. basis of the RFA. Accordingly, if an RFA has a negative basis difference, the disposition amount equals the greater of (i) any U.S. disposition gain (for this purpose, expressed as a negative amount) plus any foreign disposition loss, or (ii) unallocated basis difference. See § 1.901(m)–5T(c)(2)(ii)(B).

For the avoidance of doubt, the determination of whether there is a disposition for U.S. income tax purposes, and the amount of U.S. disposition gain or U.S. disposition loss, is made without regard to whether gain or loss is deferred or disallowed or otherwise not taken into account currently (for example, see section 267, which defers or disallows certain recognized losses, and § 1.1502–13, which provides rules for taking into account items of income, gain, deduction, and loss of members of a U.S. consolidated group from intercompany transactions). This principle also applies if foreign law has an equivalent concept whereby gain or loss that is realized and recognized is deferred or disallowed.

If an asset is an RFA by reason of a section 743(b) CAA and subsequently there is a disposition of the RFA, then for purposes of determining the disposition amount, foreign disposition gain or foreign disposition loss means the amount of gain or loss recognized for purposes of a foreign income tax on the disposition of the RFA that is allocable to the partnership interest that was transferred in the section 743(b) CAA. See § 1.901(m)–5T(c)(2)(iii). In addition, U.S. disposition gain or U.S. disposition loss means the amount of gain or loss recognized for U.S. income tax purposes on the disposition of the RFA that is allocable to the partnership interest that was transferred in the section 743(b) CAA, taking into account the basis adjustment under section 743(b) that was allocated to the RFA under section 755 in the section 743(b) CAA. See id.

VI. Successor Rules for Unallocated Basis Difference

A. General Rules

Section 1.901(m)–6T(b) provides that section 901(m) continues to apply to any unallocated basis difference with respect to an RFA after there is a transfer of the RFA for U.S. income tax purposes (successor transaction), regardless of whether the transfer is a disposition, a CAA, or a non-taxable transaction. A successor transaction does not occur if, as a result of the transfer of an RFA, the entire unallocated basis difference is taken into account because, for example, the transfer results in all realized gain or loss in the RFA being recognized for U.S. and foreign income tax purposes.

Notice 2014–44 stated that the Treasury Department and the IRS are continuing to study whether and to what extent section 901(m) should apply to an asset received in exchange for an RFA in a transaction in which the U.S. basis of the asset is determined by reference to the U.S. basis of the transferred RFA. The Treasury Department and the IRS have determined that an asset should not become an RFA solely because the U.S. basis of that asset is determined by reference to the U.S. basis of an RFA for which the asset is exchanged in a successor transaction. Accordingly, for example, if, in a successor transaction, an RFA owner transfers an RFA to a corporation in a transfer to which section 351 applies, the stock of the transferee corporation received is not an RFA even though the U.S. basis of the stock is determined under section 358 by reference to the U.S. basis of the RFA transferred.

B. Successor Transactions That Are CAAs

An asset may be an RFA with respect to multiple CAAs if a successor transaction is also a CAA (subsequent CAA). In this case, the subsequent CAA may give rise to additional basis difference. Section 1.901(m)–6T(b)(4)(i) provides generally that the unallocated basis difference with respect to a CAA that occurred prior to the subsequent CAA (referred to in the regulations as a ''prior CAA'') will continue to be taken into account under section 901(m) after the subsequent CAA.

Section 1.901(m)–6T(b)(4)(iii) provides an exception to the general rule if an RFA is subject to two section 743(b) CAAs (referred to in the regulations as a ''prior section 743(b) CAA'' and a ''subsequent section 743(b) CAA''). In this case, to the extent the same partnership interest is transferred in the section 743(b) CAAs, the RFA will be treated as having no unallocated basis difference with respect to the prior section 743(b) CAA if basis difference for the subsequent section 743(b) CAA is determined independently from the prior section 743(b) CAA. In this regard, see generally § 1.743–1(f) and proposed § 1.743–1(f)(2). If the subsequent section 743(b) CAA results from the acquisition of only a portion of the partnership interest acquired in the prior section 743(b) CAA, the transferor must equitably apportion the unallocated basis difference attributable to the prior section 743(b) CAA between the portion of the interest retained and the portion of the interest transferred. With respect to the portion transferred, the RFA will be treated as having no unallocated basis difference attributable to the prior section 743(b) CAA.

VII. Definition of Foreign Income Tax

For purposes of section 901(m), the temporary regulations define ''foreign income tax'' as any income, war profits, or excess profits tax for which a credit is allowable under section 901 or 903, other than any withholding tax determined on a gross basis as described in section 901(k)(1)(B). The Treasury Department and the IRS have determined that a withholding tax should not be subject to disallowance under section 901(m) because a withholding tax is a gross basis tax that is generally unaffected by changes in asset basis.

Effect on Other Documents

The following publications are obsolete as of December 7, 2016:

Notice 2014–44 (2014–32 I.R.B. 270) and Notice 2014–45 (2014–34 I.R.B. 388).

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), refer to the Special Analyses section of the preamble of the cross-referenced notice of proposed rulemaking published in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

Drafting Information

The principal author of these regulations is Jeffrey L. Parry of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Sections 1.901(m)–1T through –8T also issued under 26 U.S.C. 901(m)(7).

Section 1.901(m)–5T also issued under 26 U.S.C. 901(m)(3)(B)(ii). * * *

■ **Par. 2.** Section 1.901(m)–1T is added to read as follows:

§ 1.901(m)–1T Definitions (temporary).

(a) *Definitions.* For purposes of section 901(m), this section, and §§ 1.901(m)–2T through 1.901(m)–8T, the following definitions apply:

(1)–(5) [Reserved]

(6) The term *basis difference* has the meaning provided in § 1.901(m)–4T.

(7) The term *cost recovery amount* has the meaning provided in § 1.901(m)–5T(b)(2).

(8) The term *covered asset acquisition* (or *CAA*) has the meaning provided in § 1.901(m)–2T.

(9) [Reserved]

(10) The term *disposition* means an event (for example, a sale, abandonment, or mark-to-market event) that results in gain or loss being recognized with respect to an RFA for purposes of U.S. income tax or a foreign income tax, or both.

(11) The term *disposition amount* has the meaning provided in § 1.901(m)-5T(c)(2).

(12) [Reserved]

(13) The term *disregarded entity* means an entity that is disregarded as an entity separate from its owner, as described in § 301.7701–2(c)(2)(i) of this chapter.

(14) The term *fiscally transparent entity* means an entity, including a Disregarded Entity, that is fiscally transparent under the principles of § 1.894–1(d)(3) for purposes of U.S. income tax or a foreign income tax (or both).

(15)–(17) [Reserved].

(18) The term *foreign disposition gain* means, with respect to a foreign income tax, the amount of gain recognized on a disposition of an RFA in determining Foreign Income, regardless of whether the gain is deferred or otherwise not taken into account currently. Notwithstanding the foregoing, if after a section 743(b) CAA there is a disposition of an asset that is an RFA with respect to that section 743(b) CAA, foreign disposition gain has the meaning provided in § 1.901(m)–5T(c)(2)(iii).

(19) The term *foreign disposition loss* means, with respect to a foreign income tax, the amount of loss recognized on a disposition of an RFA in determining Foreign Income, regardless of whether the loss is deferred or disallowed or otherwise not taken into account currently. Notwithstanding the foregoing, if after a section 743(b) CAA there is a disposition of an asset that is an RFA with respect to that section 743(b) CAA, foreign disposition loss has the meaning provided in § 1.901(m)–5T(c)(2)(iii).

(20) The term *foreign income* means, with respect to a foreign income tax, the taxable income (or loss) reflected on a foreign tax return (as properly amended or adjusted), even if the taxable income (or loss) is reported by an entity that is a fiscally transparent entity for purposes of the foreign income tax. If, however, foreign law imposes tax on the combined income (within the meaning of § 1.901–2(f)(3)(ii)) of two or more Foreign Payors, foreign income means the combined taxable income (or loss) of such Foreign Payors, regardless of whether such income (or loss) is reflected on a single foreign tax return.

(21) The term *foreign income tax* means an income, war profits, or excess profits tax for which a credit is allowable under section 901 or 903, except that it does not include any withholding tax determined on a gross basis as described in section 901(k)(1)(B).

(22)–(25) [Reserved]

(26) The term *prior CAA* has the meaning provided in § 1.901(m)–6T(b)(2).

(27) The term *prior section 743(b) CAA* has the meaning provided in § 1.901(m)–6T(b)(4)(iii).

(28) The term *relevant foreign asset* (or *RFA*) has the meaning provided in § 1.901(m)–2T.

(29)–(32) [Reserved]

(33) The term *section 338 CAA* has the meaning provided in § 1.901(m)–2T(b)(1).

(34) The term *section 743(b) CAA* has the meaning provided in § 1.901(m)–2T(b)(3).

(35) [Reserved]

(36) The term *subsequent CAA* has the meaning provided in § 1.901(m)–6T(b)(4)(i).

(37) The term *subsequent section 743(b) CAA* has the meaning provided in § 1.901(m)–6T(b)(4)(iii).

(38) The term *successor transaction* has the meaning provided in § 1.901(m)–6T(b)(2).

(39) [Reserved]

(40) The term *unallocated basis difference* means, with respect to an RFA and a foreign income tax, the basis difference reduced by the sum of the cost recovery amounts and the disposition amounts that have been computed under § 1.901(m)–5T.

(41) The term *U.S. basis* means the adjusted basis of an asset determined for U.S. income tax purposes.

(42) [Reserved].

(43) The term *U.S. disposition gain* means the amount of gain recognized for U.S. income tax purposes on a disposition of an RFA, regardless of whether the gain is deferred or otherwise not taken into account currently. Notwithstanding the foregoing, if after a section 743(b) CAA there is a disposition of an asset that is an RFA with respect to that section 743(b) CAA, U.S. disposition gain has the meaning provided in § 1.901(m)–5T(c)(2)(iii).

(44) The term *U.S. disposition loss* means the amount of loss recognized for U.S. income tax purposes on a disposition of an RFA, regardless of whether the loss is deferred or disallowed or otherwise not taken into account currently. Notwithstanding the foregoing, if after a section 743(b) CAA there is a disposition of an asset that is an RFA with respect to that section 743(b) CAA, U.S. disposition loss has the meaning provided in § 1.901(m)–5T(c)(2)(iii).

(45) The term *U.S. taxable year* means a taxable year as defined in section 7701(a)(23).

(b) *Effective/applicability date.* (1) [Reserved].

(2) Paragraphs (a)(6), (7), (8), (10), (11), (13), (14), (18), (19), (20), (21), (26), (27), (28), (33), (34), (36), (37), (38), (40), (41), (43), (44), and (45) of this section apply to CAAs occurring on or after July 21, 2014, and to CAAs occurring before that date resulting from an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014. Paragraphs (a)(6), (7), (8), (10), (11), (13), (14), (18), (19), (20), (21), (26), (27), (28), (33), (34), (36), (37), (38), (40), (41), (43), (44), and (45) of this section also apply to CAAs occurring on or after January 1, 2011, and before July 21, 2014, other than CAAs occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, but only if the basis difference (within the meaning of section 901(m)(3)(C)(i)) in one or more RFAs with respect to the CAA had not been fully taken into account under section 901(m)(3)(B) either as of July 21, 2014, or, in the case of an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, prior to the transactions that are deemed to occur under § 301.7701–3(g) as a result of the change in classification.

(3) [Reserved].

(c) *Expiration date.* The applicability of this section expires on December 6, 2019.

■ **Par. 3.** Section 1.901(m)–2T is added to read as follows:

§ 1.901(m)–2T Covered asset acquisitions and relevant foreign assets (temporary).

(a) *In general.* Paragraph (b) of this section sets forth the transactions that are covered asset acquisitions (or CAAs). Paragraph (c) of this section provides rules for identifying assets that are relevant foreign assets (or RFAs) with respect to a CAA. Paragraph (d) of this section provides special rules for identifying CAAs and RFAs with respect to transactions to which paragraphs (b) and (c) of this section do not apply. Paragraph (e) of this section provides examples illustrating the rules of this section. Paragraph (f) of this section provides the effective/applicability date, and paragraph (g) of this section provides the expiration date.

(b) *Covered asset acquisitions.* Except as provided in paragraph (d) of this section, the transactions set forth in this paragraph (b) are CAAs.

(1) A qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies (section 338 CAA);

(2) Any transaction that is treated as an acquisition of assets for U.S. income tax purposes and as an acquisition of stock of a corporation (or the transaction is disregarded) for foreign income tax purposes;

(3) Any acquisition of an interest in a partnership that has an election in effect under section 754 (section 743(b) CAA);

(4)–(6) [Reserved].

(c) *Relevant foreign asset*—(1) *In general.* Except as provided in paragraph (d) of this section, an RFA means, with respect to a foreign income tax and a CAA, any asset (including goodwill, going concern value, or other intangible) subject to the CAA that is relevant in determining foreign income for purposes of the foreign income tax.

(2) *RFA status with respect to a foreign income tax* [Reserved].

(3) *Subsequent RFA status with respect to another foreign income tax* [Reserved].

(d) *Identifying covered asset acquisitions and relevant foreign assets to which paragraphs (b) and (c) of this section do not apply.* For transactions occurring on or after January 1, 2011, and before July 21, 2014, other than transactions occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, the transactions set forth under section 901(m)(2) are CAAs and the assets that are relevant foreign assets with respect to the CAA under section 901(m)(4) are RFAs.

(e) *Examples.* [Reserved].

(f) *Effective/applicability date*—(1) Paragraphs (a), (b)(1) through (3), and (c)(1) of this section apply to transactions occurring on or after July 21, 2014, and to transactions occurring before that date resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014. Paragraph (d) of this section applies to transactions occurring on or after January 1, 2011, and before July 21, 2014, other than transactions occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014.

(2)–(3) [Reserved]

(g) *Expiration date.* The applicability of this section expires on December 6, 2019.

■ **Par. 4.** Section 1.901(m)–3T is added and reserved to read as follows:

§ 1.901(m)–3T Disqualified tax amount and aggregate basis difference carryover (temporary). [Reserved].

■ **Par. 5.** Section 1.901(m)–4T is added to read as follows:

§ 1.901(m)–4T Determination of basis difference (temporary).

(a) *In general.* This section provides rules for determining for each RFA the basis difference that arises as a result of a CAA. A basis difference is computed separately with respect to each foreign income tax for which an asset subject to a CAA is an RFA. Paragraph (b) of this section provides the general rule for determining basis difference that references only U.S. basis in the RFA. Paragraph (c) of this section provides for an election to determine basis difference by reference to foreign basis and sets forth the procedures for making the election. Paragraph (d) of this section provides special rules for determining basis difference in the case of a section 743(b) CAA. Paragraph (e) of this section provides a special rule for determining basis difference in an RFA with respect to a CAA to which paragraphs (b) through (d) of this section do not apply. Paragraph (f) of this section provides examples illustrating the rules of this section. Paragraph (g) of this section provides the effective/applicability date, and paragraph (h) of this section provides the expiration date.

(b) *General rule.* Except as otherwise provided in paragraphs (c), (d), and (e) of this section, basis difference is the U.S. basis in the RFA immediately after the CAA, less the U.S. basis in the RFA immediately before the CAA. Basis difference is an attribute that attaches to an RFA.

(c) *Foreign basis election.* [Reserved].

(d) *Determination of basis difference in a section 743(b) CAA*—(1) *In general.* Except as provided in paragraphs (d)(2) and (e) of this section, if there is a section 743(b) CAA, basis difference is the resulting basis adjustment under section 743(b) that is allocated to the RFA under section 755.

(2) *Foreign basis election.* [Reserved].

(e) *Determination of basis difference in an RFA with respect to a CAA with respect to which paragraphs (b), (c), and (d) of this section do not apply.* For CAAs occurring on or after January 1, 2011, and before July 21, 2014, other than CAAs occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 *of this chapter* that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, basis difference in an RFA with respect to the CAA is the amount of any basis difference (within the meaning of section 901(m)(3)(C)(i)) that had not been taken into account under section 901(m)(3)(B) either as of July 21, 2014, or, in the case of an entity classification election made under § 301.7701–3 *of this chapter* that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, prior to the transactions that are deemed to occur under § 301.7701–3(g) as a result of the change in classification.

(f) *Examples.* [Reserved].

(g) *Effective/applicability date.* (1) Paragraphs (a), (b), and (d)(1) of this section apply to CAAs occurring on or after July 21, 2014, and to CAAs occurring before that date resulting from an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014. Paragraph (e) of this section applies to CAAs occurring on or after January 1, 2011, and before July 21, 2014, other than CAAs occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 *of this chapter* that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014. Taxpayers may, however, consistently apply paragraph (d)(1) of this section to all section 743(b) CAAs occurring on or after January 1, 2011. For this purpose, persons that are related (within the meaning of section

267(b) or 707(b)) will be treated as a single taxpayer.

(2)–(3) [Reserved]

(h) *Expiration date.* The applicability of this section expires on December 6, 2019.

■ **Par. 6.** Section 1.901(m)–5T is added to read as follows:

§ 1.901(m)–5T Basis difference taken into account (temporary).

(a) *In general.* [Reserved].

(b) *Basis difference taken into account under applicable cost recovery method*—(1) *In general.* [Reserved].

(2) *Determining a cost recovery amount*—(i) *General rule.* A cost recovery amount for an RFA is determined by applying the applicable cost recovery method to the basis difference rather than to the U.S. basis.

(ii) *U.S. basis subject to multiple cost recovery methods.* [Reserved].

(3) *Applicable cost recovery method.* [Reserved].

(c) *Basis difference taken into account as a result of a disposition*—(1) *In general.* [Reserved].

(2) *Determining a disposition amount*—(i) *Disposition is fully taxable for purposes of both U.S. income tax and the foreign income tax.* If a disposition of an RFA is fully taxable (that is, results in all gain or loss, if any, being recognized with respect to the RFA) for purposes of both U.S. income tax and the foreign income tax, the disposition amount is equal to the unallocated basis difference with respect to the RFA.

(ii) *Disposition is not fully taxable for purposes of U.S. income tax or the foreign income tax (or both).* If the disposition of an RFA is not fully taxable for purposes of both U.S. income tax and the foreign income tax, the disposition amount is determined under this paragraph (c)(2)(ii). See § 1.901(m)–6T for rules regarding the continued application of section 901(m) if the RFA has any unallocated basis difference after determining the disposition amount under paragraph (c)(2)(ii)(A) or (B) of this section, as applicable.

(A) *Positive basis difference.* If the disposition of an RFA is not fully taxable for purposes of both U.S. income tax and the foreign income tax, and the RFA has a positive basis difference, the disposition amount equals the lesser of:

(*1*) Any foreign disposition gain plus any U.S. disposition loss (for this purpose, expressed as a positive amount), or

(*2*) Unallocated basis difference with respect to the RFA.

(B) *Negative basis difference.* If the disposition of an RFA is not fully taxable for purposes of both U.S. income tax and the foreign income tax, and the RFA has a negative basis difference, the disposition amount equals the greater of:

(*1*) Any U.S. disposition gain (for this purpose, expressed as a negative amount) plus any foreign disposition loss, or

(*2*) Unallocated basis difference with respect to the RFA.

(iii) *Disposition of an RFA after a section 743(b) CAA.* If an RFA was subject to a section 743(b) CAA and subsequently there is a disposition of the RFA, then, for purposes of determining the disposition amount, foreign disposition gain or foreign disposition loss are specially defined to mean the amount of gain or loss recognized for purposes of the foreign income tax on the disposition of the RFA that is allocable to the partnership interest that was transferred in the section 743(b) CAA. In addition, U.S. disposition gain or U.S. disposition loss are specially defined to mean the amount of gain or loss recognized for U.S. income tax purposes on the disposition of the RFA that is allocable to the partnership interest that was transferred in the section 743(b) CAA, taking into account the basis adjustment under section 743(b) that was allocated to the RFA under section 755.

(d) *General rules for allocating and assigning a cost recovery amount or a disposition amount when the RFA owner (U.S.) is a fiscally transparent entity.* [Reserved].

(e) *Special rules for certain section 743(b) CAAs.* [Reserved]

(f) *Mid-year transactions.* [Reserved]

(g) *Reverse hybrids.* [Reserved]

(h) *Examples.* [Reserved]

(i) *Effective/applicability date.* (1) [Reserved]

(2) Paragraphs (b)(2)(i) and (c)(2) of this section apply to CAAs occurring on or after July 21, 2014, and to CAAs occurring before that date resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014. Paragraphs (b)(2)(i) and (c)(2) of this section also apply to CAAs occurring on or after January 1, 2011, and before July 21, 2014, other than CAAs occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, but only with respect to basis difference determined under § 1.901(m)–4T(e) with respect to the CAA.

(3) [Reserved]

(j) *Expiration date.* The applicability of this section expires on December 6, 2019.

■ **Par. 7.** Section 1.901(m)–6T is added to read as follows:

§ 1.901(m)–6T Successor rules (temporary).

(a) *In general.* This section provides successor rules applicable to section 901(m). Paragraph (b) of this section provides rules for the continued application of section 901(m) after an RFA that has unallocated basis difference has been transferred, including special rules applicable to successor transactions that are also CAAs or that involve partnerships. Paragraph (c) of this section provides rules for determining when an aggregate basis difference carryover of a section 901(m) payor either becomes an aggregate basis difference carryover of the section 901(m) payor with respect to another foreign payor or is transferred to another section 901(m) payor. Paragraph (d) of this section provides the effective/applicability date, and paragraph (e) of this section provides the expiration date.

(b) *Successor rules for unallocated basis difference*—(1) *In general.* Except as provided in paragraph (b)(4) of this section, section 901(m) continues to apply after a successor transaction to any unallocated basis difference attached to a transferred RFA until the entire basis difference has been taken into account as a cost recovery amount or a disposition amount (or both) under § 1.901(m)–5T.

(2) *Definition of a successor transaction.* A successor transaction occurs with respect to an RFA if, after a CAA (prior CAA), there is a transfer of the RFA for U.S. income tax purposes and the RFA has unallocated basis difference with respect to the prior CAA, determined immediately after the transfer. A successor transaction may occur regardless of whether the transfer of the RFA is a disposition, a CAA, or a non-taxable transaction for purposes of U.S. income tax. If the RFA was subject to multiple prior CAAs, a separate determination must be made with respect to each prior CAA as to whether the transfer is a successor transaction.

(3) *Special considerations.* [Reserved].

(4) *Successor transaction is a CAA*—(i) *In general.* An asset may be an RFA with respect to multiple CAAs if a successor transaction is also a CAA (subsequent CAA). Except as otherwise provided in this paragraph (b)(4), if there is a subsequent CAA, unallocated basis difference with respect to any prior CAAs will continue to be taken

into account under section 901(m) after the subsequent CAA. Furthermore, the subsequent CAA may give rise to additional basis difference subject to section 901(m).

(ii) *Foreign basis election.* [Reserved].

(iii) *Multiple section 743(b) CAAs.* If an RFA is subject to two section 743(b) CAAs (prior section 743(b) CAA and subsequent section 743(b) CAA) and the same partnership interest is acquired in both the CAAs, the RFA will be treated as having no unallocated basis difference with respect to the prior section 743(b) CAA if the basis difference for the section 743(b) CAA is determined independently from the prior section 743(b) CAA. In this regard, see generally § 1.743–1(f). If the subsequent section 743(b) CAA results from the acquisition of only a portion of the partnership interest acquired in the prior section 743(b) CAA, then the transferor will be required to equitably apportion the unallocated basis difference attributable to the prior section 743(b) CAA between the portion retained by the transferor and the portion transferred. In this case, with respect to the portion transferred, the RFAs will be treated as having no unallocated basis difference with respect to the prior section 743(b) CAA if basis difference for the subsequent section 743(b) CAA is determined independently from the prior section 743(b) CAA.

(5) *Example.* The following example illustrates the rules of paragraph (b) of this section.

Example. (i) *Facts.* USP, a domestic corporation, wholly owns CFC, a foreign corporation organized in Country A and treated as a corporation for both U.S. and Country A tax purposes. FT is an unrelated foreign corporation organized in Country A and treated as a corporation for both U.S. and Country A tax purposes. FT owns one asset, a parcel of land (Asset). Country A imposes a single tax that is a foreign income tax. On January 1, Year 1, CFC acquires all of the stock of FT in exchange for 300u in a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies (Acquisition). Immediately before the Acquisition, Asset had a U.S. basis of 100u, and immediately after the Acquisition, Asset had a U.S. basis of 300u. Effective on February 1, Year 1, FT elects to be a disregarded entity pursuant to § 301.7701–3. As a result of the election, FT is deemed, for U.S. income tax purposes, to distribute Asset to CFC in liquidation (Deemed Liquidation) immediately before the closing of the day before the election is effective pursuant to § 301.7701–3(g)(1)(iii) and (3)(ii). The Deemed Liquidation is disregarded for Country A tax purposes. No gain or loss is recognized on the Deemed Liquidation for either U.S. or Country A tax purposes.

(ii) *Result.* Under § 1.901(m)–2T(b)(1), the Acquisition by CFC of the stock of FT is a section 338 CAA. Under § 1.901(m)–2T(c)(1), Asset is an RFA with respect to Country A tax and the Acquisition, because immediately after the Acquisition, Asset is relevant in determining foreign income of FT for Country A tax purposes, and FT owned Asset when the Acquisition occurred. Under § 1.901(m)–4T(b), the basis difference with respect to Asset is 200u (300u − 100u). Under § 1.901(m)–2T(b)(2), the Deemed Liquidation is a CAA (subsequent CAA) because the Deemed Liquidation is treated as an acquisition of assets for U.S. income tax purposes and is disregarded for Country A tax purposes. Because the U.S. basis in Asset is 300u immediately before and after the Deemed Liquidation, the subsequent CAA does not give rise to any additional basis difference. The Deemed Liquidation is not a disposition under § 1.901(m)–1T(a)(10) because it did not result in gain or loss being recognized with respect to Asset for U.S. or Country A tax purposes. Accordingly, no basis difference with respect to Asset is taken into account under § 1.901(m)–5T as a result of the Deemed Liquidation, and the unallocated basis difference with respect to Asset immediately after the Deemed Liquidation is 200u (200u − 0u). Under paragraph (b)(2) of this section, the Deemed Liquidation is a successor transaction because there is a transfer of Asset for U.S. income tax purposes from FT to CFC and Asset has unallocated basis difference with respect to the Acquisition immediately after the Deemed Liquidation. Accordingly, under paragraph (b)(1) of this section, section 901(m) will continue to apply to the unallocated basis difference with respect to Asset until the entire 200u basis difference has been taken into account under § 1.901(m)–5T.

(c) *Successor rules for aggregate basis difference carryover* [Reserved].

(d) *Effective/applicability date.* (1) Paragraphs (a), (b)(1), (b)(2), (b)(4)(i), (b)(4)(iii), and (b)(5) of this section apply to CAAs occurring on or after July 21, 2014, and to CAAs occurring before that date resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014. Paragraphs (a), (b)(1), (b)(2), (b)(4)(i), (b)(4)(iii), and (b)(5) of this section also apply to CAAs occurring on or after January 1, 2011, and before July 21, 2014, other than CAAs occurring before July 21, 2014, resulting from an entity classification election made under § 301.7701–3 that is filed on or after July 29, 2014, and that is effective on or before July 21, 2014, but only with respect to basis difference determined under § 1.901(m)–4T(e) with respect to the CAA.

(2)–(3) [Reserved]

(e) *Expiration date.* The applicability of this section expires on December 6, 2019.

■ **Par. 8.** Sections 1.901(m)–7T and 1.901(m)–8T are added and reserved to read as follows:

§ 1.901(m)–7T De minimis rules. [Reserved].

§ 1.901(m)–8T Miscellaneous. [Reserved].

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: November 4, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–28755 Filed 12–6–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 38

RIN 1291–AA36

Implementation of the Nondiscrimination and Equal Opportunity Provisions of the Workforce Innovation and Opportunity Act

Correction

In rule document 2016–27737 beginning on page 87130 in the issue of Friday, December 2, 2016, make the following correction:

1. On page 87130, in the first column, after the **DATES** heading, the second line, ''December 2, 2016.'' should read ''January 3, 2017.''

[FR Doc. C1–2016–27737 Filed 12–6–16; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–1020]

RIN 1625–AA00

Safety Zone; Upper Mississippi River, St. Louis, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on the Upper Mississippi River from mile 179.2 to mile 180. The safety zone is needed to protect personnel, vessels, and the marine environment from potential

hazards created during a fireworks display on and over the navigable waterway. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative.

DATES: This rule is effective from 7:45 p.m. to 8:40 p.m. on December 31, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–1020 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 LCDR Sean Peterson, Chief of Prevention, Sector Upper Mississippi River, U.S. Coast Guard; telephone 314–269–2332, email *Sean.M.Peterson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

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 NPRM with respect to this rule because the Coast Guard was not notified of the fireworks display until November 9, 2016. After full review of the details for the planned display, the Coast Guard determined action is needed to protect people and property from the safety hazards associated with the fireworks display on the Upper Mississippi River (UMR) near St. Louis, MO. It is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule; we must establish this safety zone by December 31, 2016.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of the rule is contrary to the public interest as it would delay the effectiveness of the temporary safety zone needed to respond to potential related safety hazards until after the planned 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 COTP has determined that potential hazards associated with the fireworks display will be a safety concern before, during, and after the display. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone from 7:45 p.m. to 8:40 p.m. on December 31, 2016. The safety zone will cover all navigable waters between miles 179.2 and 180 on the UMR in St. Louis, MO. Exact times of the closures during this 55 minute period will be communicated to mariners using broadcast and local notice to mariners. The safety zone is intended to ensure the safety of vessels and these navigable waters before, during and after the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. 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.

This temporary final rule establishes a safety zone impacting a less than one mile area on the UMR for a limited time period less than one hour. During the enforcement period, vessels are prohibited from entering into or remaining within the safety zone unless specifically authorized by the COTP or other designated representative. Based on the location, limited safety zone area, and short duration of the enforcement period, this rule does not pose a significant regulatory impact. Additionally, notice of the safety zone will be made via broadcast and local notice to mariners.

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 Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting less than one hour that will prohibit entry from mile 179.2 to mile 180 on the UMR. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and 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.T08–1020 to read as follows:

§ 165.T08–1020 Safety Zone; Upper Mississippi River, St. Louis, MO.

(a) *Location.* The following area is a safety zone: All waters of the Upper Mississippi River between miles 179.2 to 180, St. Louis, MO.

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

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative via VHF–FM channel 16, or through Coast Guard Sector Upper Mississippi River at 314–269–2332. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement periods.* This section will be enforced from 7:45 p.m. to 8:40 p.m. on December 31, 2016.

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

Dated: December 1, 2016.

M.L. Malloy,

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

[FR Doc. 2016–29315 Filed 12–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–1034]

RIN 1625–AA00

Safety Zone, Delaware River; Marcus Hook, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Delaware River in the vicinity of Marcus Hook, Pennsylvania. The safety zone will temporarily restrict vessel traffic from transiting or anchoring in a portion of the Delaware River while rock blasting, dredging, and rock removal operations are being conducted to facilitate the Delaware River Main Channel Deepening project for the main navigational channel of the Delaware River. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by rock blasting, dredging, and rock removal operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port or his designated representatives.

DATES: This rule is effective without actual notice from December 7, 2016 through March 15, 2017. For the purposes of enforcement, actual notice

will be used from December 1, 2016, through December 7, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type USCG–2016–1034 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 about this rule, call or email Marine Science Technician First Class Tom Simkins, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division, Coast Guard; telephone (215) 271–4889, email *Tom.J.Simkins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are impracticable, unnecessary, or contrary to the public interest. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impractical and contrary to the public interest because environmental restrictions put in place by the National Marine Fisheries Service to protect Shortnose and Atlantic sturgeon require all blasting operations to be conducted between December 1, 2016, and March 15, 2017. Due to the criticality of this phase of the Delaware River Main Channel Deepening project, immediate action is needed to accommodate operations while also ensuring vessels can safely transit through Marcus Hook Range in the Delaware River during this time. Going forward without establishing a safety zone would expose mariners and the public to unnecessary dangers associated with rock blasting, dredging, and rock removal operations. It is impracticable to publish an NPRM because the Coast Guard must establish this safety zone by December 1, 2016. The final details of the rock blasting, dredging, and rock removal operation were not received until November 23, 2016. Publishing an NPRM would be contrary to the public interest since immediate action is necessary to protect the public safety from rock blasting, dredging, and rock removal operations.

For similar reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. As noted above, blasting operations must be conducted between December 1, 2016, and March 15, 2017. Due to the need for immediate action, the restriction is necessary to protect life and property. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels, and enhancing public and maritime safety.

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 has determined that potential hazards associated with rock blasting, dredging, and rock removal operations starting December 1, 2016, will be a safety concern for anyone within 500 yards of rock blasting, dredging, and rock removal operations. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the operational area.

IV. Discussion of the Rule

This rule establishes a safety zone between December 1, 2016, and March 15, 2017. The safety zone will cover all navigable waters in the Delaware River within 500 yards of vessels and machinery being used by personnel to conduct rock blasting, dredging, and rock removal operations in the vicinity of Marcus Hook, PA, between the southern end of Marcus Hook Anchorage to the western end of Little Tinicum Island, at the entrance to Darby Creek. The safety zone will be enforced in an area and in a manner that does not conflict with transiting commercial and recreational traffic, except for the short periods of time when explosive detonation evolutions are being conducted. The blasting detonations will not occur more than three times a day. At all other times, at least one side of the main navigational channel will be open for vessels to transit.

The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while operations are being conducted. For the duration of the project, in the vicinity of the rock blasting, rock removal, and dredging operation, one side of the main navigational channel will be closed. Vessels wishing to transit the safety zone in the main navigational channel may do so if they can make satisfactory passing arrangements with drill boat APACHE or the dredge TEXAS in accordance with the Navigational Rules in 33 CFR subchapter E via VHF–FM channel 13 at least 30 minutes prior to arrival. If vessels are unable to make satisfactory passing arrangements with the drill boat APACHE or the dredge TEXAS, they may request permission from the Captain of the Port, or his designated representative, on VHF–FM channel 16. All vessels must operate at the minimum safe speed necessary to maintain steerage and reduce wake.

No vessels may transit through the safety zone during times of explosives detonation. During rock blasting detonation vessels will be required to maintain a 500 yard distance from the drill boat APACHE. The drill boat APACHE will make broadcasts, via VHF–FM channels 13 and 16, at 15 minutes, 5 minutes, and 1 minute prior to detonation, as well as a countdown to detonation on VHF–FM channel 16. Sector Delaware Bay will ensure significant notice will be given to the maritime community of dates and times of blasting via broadcast notice to mariners on VHF–FM channel 16. After every explosive detonation a survey will be conducted to ensure the navigational channel is clear for vessels to transit. The drill boat APACHE will broadcast, via VHF–FM channel 13 and 16, when the survey has been completed and the channel is clear to transit. Vessels wishing to transit the safety zone in the main navigational channel may do so if they can make satisfactory passing arrangements with drill boat APACHE or the dredge TEXAS in accordance with the Navigational Rules in 33 CFR subchapter E via VHF–FM channel 13 at least 30 minutes prior to arrival. If vessels are unable to make satisfactory passing arrangements with the drill boat APACHE or the dredge TEXAS, they may request permission from the Captain of the Port, or his designated representative, on VHF–FM 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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. 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.

This regulatory action determination is based on the size, location, duration, and traffic management of the safety zone. The Coast Guard does not anticipate a significant economic impact because the safety zone will be enforced in an area and in a manner that does not conflict with transiting commercial and recreational traffic, except for the short periods of time when explosive detonation evolutions are being conducted. The blasting detonations will not occur more than three times a day. At all other times, at least one side of the main navigational channel will be open for vessels to transit. Moreover, the Coast Guard will work in coordination with the pilots to ensure vessel traffic is limited during the times of detonation and Broadcast Notice to Mariners are made via VHF–FM marine channel 13 and 16 when blasting operations will occur.

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 anchor in or 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 Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone in force from December 1, 2016, through March 15, 2017, that prohibits entry within 500 yards of vessels and machinery being used by personnel conducting rock blasting, dredging, and rock removal operations in the Delaware River near Marcus Hook, PA between the southern end of Marcus Hook Anchorage to the western end of Little Tinicum Island, at the entrance to Darby Creek. It is categorically excluded from further review under paragraph 34(g) of figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this 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.

H. Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

List of Subjects 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR 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 temporary § 165.T05–1034, to read as follows:

§ 165.T05–1034 Safety Zone, Delaware River; Marcus Hook, PA.

(a) *Regulated area.* The following area is a safety zone: All the waters of the Delaware River within 500 yards of vessels and machinery performing rock blasting, rock removal, and dredging operations, in the vicinity of Marcus Hook, PA, between the southern end of Marcus Hook Anchorage to the western end of Little Tinicum Island, at the entrance to Darby Creek.

(1) Vessels wishing to transit the safety zone in the main navigational channel may do so if they can make satisfactory passing arrangements with the drill boat APACHE or the dredge TEXAS in accordance with the Navigational Rules in 33 CFR subchapter E via VHF–FM channel 13 at least 30 minutes prior to arrival. If vessels are unable to make satisfactory passing arrangements with the drill boat APACHE or the dredge TEXAS, they may request permission from the Captain of the Port, or his designated representative, on VHF–FM channel 16.

(2) The operator of any vessel requesting to transit through the safety zone shall proceed as directed by the drill boat APACHE, the dredge TEXAS or the designated representative of the Captain of the Port and must operate at the minimum safe speed necessary to maintain steerage and reduce wake.

(3) No vessels may transit through the safety zone during times of explosives detonation. During rock blasting detonation vessels will be required to maintain a 500 yard distance from the drill boat APACHE. The drill boat APACHE will make broadcasts, via VHF–FM Channel 13 and 16, at 15 minutes, 5 minutes, and 1 minute prior to detonation, as well as a countdown to detonation on VHF–FM Channel 16.

(4) After every explosive detonation a survey will be conducted to ensure the navigational channel is clear for vessels to transit. The drill boat APACHE will broadcast, via VHF–FM channel 13 and 16, when the survey has been completed and the channel is clear to transit. Vessels requesting to transit through the safety zone shall proceed as directed by the designated representative of the Captain of the Port and contact the drill boat APACHE on VHF–FM channel 13 to make safe passing arrangements.

(b) *Definitions.* As used in this section:

Captain of the Port means Captain of the Port Delaware Bay. The Captain of the Port is also the Commander, U.S. Coast Guard Sector Delaware Bay, Philadelphia, PA.

Captain of the Port Delaware Bay means the Commander, U.S. Coast Guard Sector Delaware Bay, Philadelphia, PA.

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Delaware Bay to assist in enforcing the safety zone described in paragraph (a) of this section.

(c) *Enforcement.* The U.S. Coast Guard may be assisted by Federal, State and local agencies in the patrol and enforcement of the zone.

(d) *Enforcement period.* This rule will be enforced from December 01, 2016, through March 15, 2017, unless cancelled earlier by the Captain of the Port.

Dated: December 1, 2016.

Benjamin A. Cooper,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2016–29261 Filed 12–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–1025]

RIN 1625–AA87

Security Zone; Kailua Bay, Oahu, HI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone for the protection of a Very Important Person (VIP). This VIP will be staying on beachfront property in close proximity to Kailua Bay. It is necessary to restrict waterway access to vessels and persons to prevent waterside threats to the VIP. The security zone encompasses two primary areas from the surface of the water to the ocean floor: The navigable waters of the Kawainui Canal, beginning at the North Kalaheo Avenue Road Bridge and continuing northeast into Kailua Bay; and the navigable waters of Kailua Bay beginning at Kapoho Point and extending in a southwesterly direction to the shore boundary of a property located at 123 Kailuana Loop, Kailua, HI 96734. Entry of persons or vessels into the security zone is prohibited unless authorized by the Captain of the Port (COTP) Honolulu or a designated representative.

DATES: This rule is effective from 8 a.m. (HST) on December 14, 2016, through 8 a.m. (HST) on January 4, 2017. If the security zone is terminated prior to January 4, 2017, the Coast Guard will provide notice via a broadcast notice to mariners.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2016–1025. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–1025 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Nicolas Jarboe, Waterways Management Division, U.S. Coast Guard Sector Honolulu; telephone (808) 541–4359, email *Nicolas.a.jarboe@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive Order
FR Federal Register
NPRM Notice of proposed rulemaking
TFR Temporary final rule
Pub. L. Public Law
§ Section
U.S.C. United States Code
VIP Very Important Person

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) [5 U.S.C. 553 (b)]. This provision authorizes an agency to issue a rule without prior notice and opportunities to comment when the agency, for good cause, finds those procedures are ''impractical, unnecessary, or contrary to the public interest.'' Under 5 U.S.C.

553(d)(3), the Coast Guard finds that good cause exists for not publishing a Notice of Proposed Rulemaking (NPRM) and for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard further finds it impractical to issue an NPRM with respect to this rule because details of the VIP's travel to Hawaii were not provided to the Coast Guard until November 13, 2016, preventing the Coast Guard from completing full notice-and-comment rulemaking procedures. Publishing an NPRM and delaying the effective date would be contrary to the security zone's intended objectives, including but not limited to protection of the VIP, mitigation of potential terrorist risks, and enhancing public and maritime security. Publishing a NPRM and delaying the effective date would be contrary to the public interest since the occasion would occur before a notice-and-comment rulemaking could be completed, thereby jeopardizing the safety of the VIP. The COTP Honolulu finds this temporary security zone must be effective by December 14, 2016 to ensure the safety of the VIP during his visit to the Kailua Bay area on the eastern coast of Oahu, Hawaii.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 33 U.S.C. 1231. From December 14, 2016 through January 4, 2017, a VIP of the United States of America plans to visit the Kailua Bay area on Oahu, Hawaii. The security zone encompasses two primary areas from the surface of the water to the ocean floor: (1) The navigable waters of the Kawainui Canal, beginning at the North Kalaheo Avenue Road Bridge and continuing northeast into Kailua Bay; and (2) the navigable waters of Kailua Bay beginning at Kapoho Point and extending in a southwesterly direction to the shore boundary of a property located at 123 Kailuana Loop, Kailua, HI 96734. The COTP of Honolulu has determined the potential risks associated with the VIP's visit to the Kailua Bay area render a security zone necessary to ensure the VIP's safety. Entry of persons or vessels into the security zone is prohibited unless expressly authorized by the COTP of Honolulu or a designated representative.

IV. Discussion of Comments, Changes, and the Rule

This temporary final rule establishes a security zone from 8 a.m. (HST) on December 14, 2016, through 8: a.m. (HST) on January 4, 2017. The security zone encompasses two primary areas from the surface of the water to the ocean floor: (1) The navigable waters of the Kawainui Canal, beginning at the North Kalaheo Avenue Road Bridge and continuing northeast into Kailua Bay; and (2) the navigable waters of Kailua Bay beginning at Kapoho Point and extending in a southwesterly direction to the shore boundary of a property located at 123 Kailuana Loop, Kailua, HI 96734.

Two (2) shore-side markers will be placed in proximity of the security zone along the security zone boundary and one (1) orange boom will be placed at the canal boundary at the North Kalaheo Avenue Road Bridge as visual aids for mariners and public to approximate the zone. An illustration of the security zone will be made available on *www.regulations.gov* in docket for this rulemaking, USCG–2016–1025. No vessel or person will be permitted to enter the security zone without express authorization from the COTP Honolulu or his designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

A. Regulatory Planning and Review

E.O. 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. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Coast Guard expects the economical impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of the Department of Homeland Security (DHS) is unnecessary. This expectation is based on the limited duration of the zone, the limited geographic area affected by it, and the lack of commercial vessel traffic affected by the zone. This rule has not been designated a ''significant regulatory action,'' under E.O. 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

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 security 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 E.O. 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 executive order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, 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. 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 the Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are 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, and 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. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

■ 2. Add § 165.T14–1030 to read as follows:

§ 165.T14–1030 Security Zone; Kailua Bay, Oahu, HI.

(a) *Location.* The security zone area is located within the COTP Zone (See 33 CFR 3.70–10) and encompasses two primary areas from the surface of the water to the ocean floor: The navigable waters of the Kawainui Canal, beginning at the North Kalaheo Avenue Road Bridge and continuing northeast into Kailua Bay; and the navigable waters of Kailua Bay beginning at Kapoho Point and extending in a southwesterly direction to the shore boundary of a property located at 123 Kailuana Loop, Kailua, HI 96734. The geographic coordinates of the zone include the navigable waters of the Kawainui Canal beginning at a point 21°24′56″ N., 157°44′58″ W., then extending to 21°25′27″ N., 157°44′21″ W. (Kapoho Point) including all the waters to the west of a straight line to 21°25′11″ N., 157°44′39″ W., and extending back to the original point 21°24′56″ N., 157°44′58″ W.

(b) *Effective period.* This rule is effective from 8 a.m. (HST) on December 14, 2016, through 8 a.m. (HST) on January 4, 2017.

(c) *Regulations.* The general regulations governing security zones contained in 33 CFR 165.33 apply to the security zone created by this temporary final rule.

(1) All persons and vessels are required to comply with the general regulations governing security zones found in 33 CFR part 165.

(2) Entry into or remaining in this security zone is prohibited unless authorized by the COTP Honolulu or his designated representative.

(3) Persons or vessels desiring to transit the security zone identified in paragraph (a) of this section may contact the COTP of Honolulu through his designated representatives at the Command Center via telephone: (808) 842–2600 and (808) 842–2601; fax: (808) 842–2642; or on VHF channel 16 (156.8 Mhz) to request permission to transit the security zone. If permission is granted, all persons and vessels must comply with the instructions of the COTP Honolulu or his designated representative and proceed at the minimum speed necessary to maintain a safe course while in the security zone.

(4) The U.S. Coast Guard may be assisted in the patrol and enforcement of the security zone by Federal, State, and local agencies.

(d) *Notice of enforcement.* The COTP Honolulu will provide notice of enforcement of the security zone described in this section by verbal radio broadcasts, written notice to mariners, and general public outreach.

(e) *Definitions.* As used in this section, designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the COTP to assist in enforcing the security zone described in paragraph (a) of this section.

Dated: December 1, 2016.

M.C. Long,

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

[FR Doc. 2016–29317 Filed 12–6–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP87

Extension of Pharmacy Copayments for Medications

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its medical regulations concerning the copayment required for certain medications. This rulemaking freezes copayments at the current rate for veterans in priority groups 2 through 8 through February 26, 2017.

DATES: *Effective Date:* This rule is effective on December 7, 2016.

Comment date: Comments must be received on or before February 6, 2017.

ADDRESSES: Written comments may be submitted by email through *http://www.regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to ''RIN 2900–AP87-Copayments for Medications in

2017.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bridget Souza, Office of Community Care (10D), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 382–2537. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1722A(a), VA must require veterans to pay at least a $2 copayment for each 30-day supply of medication furnished on an outpatient basis for the treatment of a non-service-connected disability or condition unless a veteran has a service-connected disability rated 50 percent or more, is a former prisoner of war, or has an annual income at or below the maximum annual rate of VA pension that would be payable if the veteran were eligible for pension. Under 38 U.S.C. 1722A(b), VA ''may,'' by regulation, increase that copayment amount and establish a maximum annual copayment amount (a ''cap''). We have consistently interpreted section 1722A(b) to mean that VA has discretion to determine the appropriate copayment amount and annual cap amount for medication furnished on an outpatient basis for covered treatment, provided that any decision by VA to increase the copayment amount or annual cap amount is the subject of a rulemaking proceeding. We have implemented this statute in 38 CFR 17.110.

Under 38 CFR 17.110(b)(1), veterans are obligated to pay VA a copayment for each 30-day or less supply of medication provided by VA on an outpatient basis (other than medication administered during treatment). Under the current regulation, the copayment amount for veterans in priority groups 2 through 6 of VA's health care system is $8 through December 31, 2016. 38 CFR 17.110(b)(1)(i). The copayment amount for veterans in priority groups 7 and 8 is $9 through December 31, 2016. 38 CFR 17.110(b)(1)(ii). Thereafter, the copayment amount for all affected veterans is to be established using a formula based on the prescription drug component of the Medical Consumer Price Index (CPI–P), set forth in 38 CFR 17.110(b)(1)(iii). Using this methodology would generally result in increased medication prices for veterans.

Currently § 17.110(b)(2) also includes a ''cap'' on the total amount of copayments in a calendar year for a veteran enrolled in one of VA's health care enrollment system priority groups 2 through 6. Through December 31, 2016, the annual cap is set at $960. Thereafter, the cap is to increase ''by $120 for each $1 increase in the copayment amount'' applicable to veterans in priority categories 2 through 6.

On October 27, 2014, we published an interim final rulemaking that ''froze'' copayments for veterans in priority categories 2 through 6 at $8 and for veterans in priority groups 7 and 8 at $9, through December 31, 2015. 79 FR 63819. This interim final rule was made final on September 16, 2015. 79 FR 55545. In that final rulemaking, we extended the copayment freeze to be effective through December 31, 2016. We stated that this extended timeframe would permit the freeze to be in effect all of calendar year 2016 for the continued benefit of veterans, and would allow VA to continue to develop and publish proposed and final rules to implement a tiered copayment structure for certain medications, which will further align VA's medication copayment structure with other Federal agencies and the commercial sector. In these rulemakings, we stated that this freeze was appropriate because failure to take the action would result in higher copayments, and, as described in prior rulemakings, higher copayments reduced the utilization of VA pharmacy benefits and caused VA patients to instead rely on external providers for medications. 79 FR 63820. We continue to believe this to be the case. The ability to ensure that medications are taken as prescribed is essential to effective health care management. VA can monitor whether its patients are refilling prescriptions at regular intervals while also checking for medications that may interact with each other when these prescriptions are filled by VA. When both VA and non-VA providers are issuing prescriptions to a veteran, there is a greater risk of adverse interactions and harm to the patient because it is more difficult for each provider to assess whether the patient is taking any other medications.

On January 5, 2016, we published a proposed rule that would establish a tiered medication copayment structure. 81 FR 196. In that proposed rule, we indicated that VA intended to publish a final rule that would make the proposed changes effective January 1, 2017. VA proposed an effective date of January 1, 2017 based on our assumption that the necessary system changes would be in place by that date to allow us to publish a final rule implementing a tiered medication copayment structure. VA will be unable to meet that timeline. However, VA thinks that the necessary changes will be in place in February 2017, and that a final rule establishing a tiered medication copayment regime can be published with an effective date of February 27, 2017.

In this rulemaking, we are removing December 31, 2016, in each place it appears in paragraphs (b)(1)(i)–(iii) and (b)(2), and inserting February 26, 2017, to continue to keep copayment rates and caps at their current levels until the tiered copayment system is established.

If we fail to extend the medication copayment freeze past December 31, 2016, affected veterans would be subject to increased medication copayments until such time as the anticipated final rule implementing the tiered medication copayment structure is effective. In that case, beginning January 1, 2017, VA would use the CPI–P methodology in § 17.110(b)(1)(iii) to determine whether to increase copayments and calculate any mandated increase in the copayment amount for veterans in priority groups 2 through 8. At that time, the copayment amounts would be adjusted to a higher rate based on changes in the CPI–P over the past five years, and the annual copayment cap would also be raised by $120 for each $1 increase in the copayment amount. The end result would be increased medication copayments, and a higher annual cap on copayments until the effective date of the anticipated final rule implementing tiered medication copayments. VA believes this would not only have an adverse financial effect on veterans subject to medication copayments, but would also cause unnecessary confusion by making two changes to veterans' medication copayment amounts over a two-month period. Thus, the intended effect of this interim final rule is to prevent increases in copayment amounts and the copayment cap for veterans in priority groups 2 through 8 until VA has published a final rule establishing a new copayment structure. At that time, veterans' copayments will be determined according to the methodology contained in the final rule that VA will publish to establish a tiered copayment system. If VA has not established a new tiered copayment system by the end of February, copayments and the copayment cap will increase as prescribed in current

§ 17.110(b) in the absence of further rulemaking.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to dispense with the opportunity for advance notice and opportunity for public comment and good cause to publish this rule with an immediate effective date. As stated above, this rule freezes at current rates the prescription drug copayment that VA charges certain veterans. The Secretary finds that it is impracticable and contrary to the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. If the medication copayment freeze is not extended, on January 1, 2017, affected veterans would be subject to increased medication copayments based on changes to the CPI–P since 2010, as well as an upward adjustment to the annual copayment cap. VA believes that this might cause a significant financial hardship for those affected veterans and may decrease patient adherence to medical plans and have other unpredictable negative health effects. Further, VA believes that failing to extend the current medication copayment freeze, without interruption, would likely result in confusion for the public and affected veterans because the new tiered medication copayment regime will go into effect within a relatively short period of time. Lastly, allowing the current medication copayment freeze to expire on December 31, 2016, would create programmatic issues that would be difficult for VA to administratively manage. Within a 60-day period IT algorithms that are currently in place would have to be removed, new copayment amounts and annual cap amounts would have to be calculated and implemented along with the necessary system changes, followed by application of the new IT changes necessary for establishing a new tiered medication copayment scheme.

For the above reasons, the Secretary issues this rule as an interim final rule. VA will consider and address comments that are received within 60 days of the date this interim final rule is published in the **Federal Register**.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this interim final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This interim final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this interim final rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This interim final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This interim final rule will temporarily freeze the copayments that certain veterans are required to pay for prescription drugs furnished by VA. This interim rule directly affects individual VA patients and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the **Federal Register** for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs,

approved this document on October 3, 2016, for publication.

Dated: December 2, 2016.

Michael Shores,

Acting Director, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

Sections 17.640 and 17.647 also issued under Public Law 114–2, sec. 4.

Sections 17.641 through 17.646 also issued under 38 U.S.C. 501(a) and Public Law 114–2, sec. 4.

§ 17.110 [Amended]

■ 2. Amend § 17.110 as follows:

■ a. In paragraphs (b)(1)(i), (ii), and (iii), remove all references to ''December 31, 2016'' and add in each place ''February 26, 2017''.

■ b. In paragraph (b)(2), remove all references to ''December 31, 2016'' and add in each place ''February 26, 2017''.

[FR Doc. 2016–29337 Filed 12–6–16; 8:45 am]

BILLING CODE 8320–01–P

POSTAL REGULATORY COMMISSION

39 CFR Parts 3015 and 3060

[Docket No. RM2016–13; Order No. 3641]

Changes to Attributable Costing

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a set of final rules amending some existing Commission rules related to attributable costing. The final rules are consistent with methodology changes approved by the Commission. Relative to the proposed rules, one rule was revised to alleviate confusion and another revision was administrative in nature.

DATES: Effective January 6, 2017.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Regulatory History

81 FR 63448 (Sept. 15, 2016).

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I. Introduction

On September 9, 2016, the Commission issued proposed rules consisting of necessary changes, resulting from Order No. 3506, that specifically define or describe attributable costs.[1] For the reasons discussed below, the Commission adopts final rules on this topic, with minor revisions to the proposed rules as discussed in chapter IV.

II. Background

On September 9, 2016, the Commission issued Order No. 3506 after consideration of a United Parcel Service, Inc. (UPS) petition which sought to make changes to the methodologies employed by the Postal Service to account for the costs of the Postal Service's products in its periodic reports.[2] In Proposal One, UPS recommended that the Postal Service calculate and attribute inframarginal costs to individual products in addition to the currently attributed volume-variable and product-specific fixed costs. Petition, Proposal One at 1. Proposal Two dealt with reclassifying some fixed costs as fully or partially variable, and attributing those costs to products. Petition, Proposal Two at 1. UPS also filed a third proposal, which requested a review of competitive products' share of institutional costs.[3]

The instant rulemaking stems from the Commission's findings in Order No. 3506 on Proposal One. In that order, the Commission found that a portion of inframarginal costs (those inframarginal costs calculated as part of a product's incremental cost) have a reliably identifiable causal relationship to products. Order No. 3506 at 61. Therefore, pursuant to Order No. 3506, attributable costs must also include those inframarginal costs calculated as part of a competitive product's incremental costs (in addition to a product's volume-variable costs and product-specific fixed costs).[4]

As noted above, on October 19, 2016, the Commission issued the Errata to clarify the definition of inframarginal costs described in Order No. 3506. *See* Errata. Generally, when defining inframarginal costs, the Errata replaced the phrase ''do not vary directly with volume,'' with the phrase ''are not volume-variable costs.'' *Id.* at 1–2. The revised definition of inframarginal costs does not impact the Commission's findings in Order No. 3506. However, the definition cited in Order No. 3507, ''[i]nframarginal costs are variable costs that do not vary directly with volume,'' would now be cited as ''[i]nframarginal costs are variable costs that are not volume-variable costs.'' *Id.* at 1; Order No. 3507 at 4; *see also* Order No. 3506 at 10.

III. Review and Analysis of Comments

On October 17, 2016, the Commission received comments from Amazon Fulfillment Services, Inc. (Amazon),[5] the Public Representative,[6] and the Postal Service.[7] On October 18, 2016, the Commission received comments from UPS[8] and, on October 20, 2016, it

[1] Notice of Proposed Rulemaking on Changes Concerning Attributable Costing, September 9, 2016 (Order No. 3507). *See also* Docket No. RM2016–2, Order Concerning United Parcel Service, Inc.'s Proposed Changes to Postal Service Costing Methodologies (UPS Proposals One, Two, and Three), September 9, 2016 (Order No. 3506). Discussed in greater detail below, the Commission issued an errata related to Order No. 3506. Docket No. RM2016–2, Notice of Errata, October 19, 2016 (Errata). Any reference to Order No. 3506 refers to the updated version including the changes identified in the Errata.

[2] *See generally* Order No. 3506. *See also* Docket No. RM2016–2, Petition of United Parcel Service, Inc. for the Initiation of Proceedings to Make Changes to Postal Service Costing Methodologies, October 8, 2015 (Petition).

[3] Petition, Proposal Three at 1. The Commission declined to consider Proposal Three as it planned to initiate its 5-year review pursuant to 39 U.S.C. 3633(b) following Order No. 3506's issuance. Order No. 3506 at 124, 125; *see also* Docket No. RM2017–1, Order No. 3624, Advance Notice of Proposed Rulemaking to Evaluate the Institutional Cost Contribution Requirement for Competitive Products, November 22, 2016.

[4] On October 7, 2016, UPS appealed Order No. 3506 to the United States Court of Appeals for the District of Columbia Circuit. *United Parcel Service, Inc.* v. *Postal Regulatory Commission,* No. 16–1354 (D.C. Cir. filed Oct. 7, 2016) (Case No. 16–1354).

[5] Comments of Amazon Fulfillment Services, Inc., October 17, 2016 (Amazon Comments).

[6] Public Representative Comments, October 17, 2016 (PR Comments).

[7] Comments of the United States Postal Service in Response to Order No. 3507, October 17, 2016 (Postal Service Comments).

[8] United Parcel Service, Inc.'s Comments on Notice of Proposed Rulemaking on Changes Concerning Attributable Costing, October 18, 2016 (UPS Comments). UPS also filed a motion for late

received comments from Valpak Direct Marketing Systems, Inc. and the Valpak Franchise Association, Inc. (Valpak).[9] Comments and the Commission's analysis of those comments are discussed below. In addition, Commission analysis related to revisions to the proposed rules is discussed in chapter IV of this Order.

a. Amazon

Comments. Amazon supports adoption of the proposed rules but requests clarification concerning statements made in Order No. 3507 and suggests revisions to proposed § 3015.7(b). Amazon Comments at 1. Amazon seeks clarification concerning the Commission's statement ''[w]hile the Commission found that inframarginal costs are causally related to products, it determined inframarginal costs cannot be reliably identified, which is a necessary component of cost attribution.'' *Id.* at 1–2; *see* Order No. 3507 at 4 (citing Order No. 3506 at 56). Amazon argues that the statement is unclear considering the Commission's finding in Order No. 3506, that only *some* inframarginal costs are causally related to individual products. Amazon Comments at 2; *see also* Order No. 3506 at 35, 45–51, 55 (emphasis added).

Amazon also seeks clarification on the description of inframarginal costs (variable costs that do not vary directly with volume) in Order No. 3507. Amazon Comments at 2; *see also* Order No. 3507 at 4. Amazon states inframarginal costs should not be described based on a direct or indirect relationship between volume and cost, but instead should be described based on a causal relationship between the level of costs and the marginal unit of output of a product. Amazon Comments at 2–3.

Finally, Amazon suggests revisions to proposed 3015.7(b) in order to cure what it believes is a circular reference in the rule. *Id.* at 3. The proposed rule defines a product's attributable cost as its ''. . . incremental costs, which is the sum of volume-variable costs, product-specific costs, and those inframarginal costs calculated as part of a competitive product's incremental costs. . . .'' *Id.* (quoting proposed § 3015.7(b)). Because the term ''incremental cost'' appears both as a defined term, and as an element of the definition, Amazon asserts that this reference is circular. *Id.* Amazon provides a revised definition and states its adoption ''would avoid needless confusion, and would allow the appropriate amount of inframarginal costs to be attributed to each product.'' *Id.* at 4.

Commission analysis. The Commission confirms that in Order No. 3506 it found only the portion of inframarginal costs calculated as part of an individual product's incremental costs is causally related and reliably identifiable to individual products, and therefore can be linked to those products. Order No. 3506 at 35, 45–51, 55–56. In addition, the Commission notes that the Errata provided clarification as to the definition of inframarginal costs. *See supra* at 3; *see generally* Errata. In addition, the Commission recognizes the potential confusion related to the references to incremental costs in proposed § 3015.7(b). Clarifying changes to proposed § 3015.7(b) are discussed in chapter IV of this Order.

b. Public Representative

Comments. The Public Representative states that the proposed rules conform to Order No. 3506, but that the Commission should discuss the meaning of ''to the extent that incremental cost data are unavailable,'' in proposed § 3015.7(a), in order to ''forestall potential attempts to game the outcome.'' PR Comments at 2–3. In addition, the Public Representative suggests a rearrangement of the phrase ''to calculate attributable costs'' in proposed § 3015.7(b) for clarification and readability purposes. *Id.* at 7.

Finally, the Public Representative cites to his comments in Docket No. RM2016–2 and, just as in that docket, maintains that a review of compliance with section 703(d) of the Postal Accountability and Enhancement Act (PAEA) is necessary in order to consider changes to attributable costs and revise related rules.[10] He argues Order No. 3507 modifies rules under 39 U.S.C. 3633 and must therefore follow the requirements of section 703(d). PR Comments at 6.

Commission analysis. The phrase ''to the extent that incremental cost data are unavailable'' stems from the original establishment of part 3015 in Docket No. RM2007–1 and remains unchanged in § 3015.7.[11] The Commission did not propose any revisions related to this particular phrase in Order No. 3507 and offers the following explanation. Currently, incremental cost data are available for all products with the exception of international mail. Incremental costs for international mail are not available because its cost pools are not sufficiently disaggregated between market dominant and competitive products. Order No. 3506, Appendix A at 18. The method of calculating incremental costs approved in Docket No. RM2010–4 is applicable to all domestic products, whether market dominant or competitive.[12] Because international mail makes up a small percentage of volume, volume-variable costs, and product-specific costs relative to all mail, it is unlikely that the inability to calculate its incremental costs would allow the Postal Service to ''game the outcome'' and materially reduce the level of cost attribution.

The Commission has previously discussed section 703(d) and its applicability to Order Nos. 3506 and 3507. In Order No. 3506, the Commission distinguished its review of attributable costing as a change in analytical principles pursuant to 39 U.S.C. 3652 rather than a proceeding under 39 U.S.C. 3633. Order No. 3506 at 117–122; *see also* 39 U.S.C. 3652 and 3633. In Order No. 3507, the Commission determined that ''the proposed rules in this instance did not trigger the requirement to consider the net economic effect'' because the proposed rules involve conforming changes required by the Commission's action taken in Docket No. RM2016–2 and therefore is required by law. Order No. 3507 at 3 n.4. It also stated that because the proposed revisions are required by law, ''any consideration of the 'net economic effect' recommendations identified in

acceptance of its comments. Motion of the United Parcel Service, Inc. for Late Acceptance of Filing of Comments in Response to RM2016–13, October 18, 2016 (UPS Motion). The UPS Motion is granted.

[9] Valpak Direct Marketing Systems, Inc. and the Valpak Franchise Association, Inc. Comments on Changes Concerning Attributable Costing, October 20, 2016 (Valpak Comments). Valpak also filed a motion for late acceptance of its comments. Valpak Direct Marketing Systems, Inc. and the Valpak Franchise Association, Inc. Motion for Late Acceptance of Comments, October 20, 2016 (Valpak Motion). The Valpak Motion is granted.

[10] *Id.* at 3. ''Uncodified section 703 of the PAEA, Public Law 109–435, 120 Stat. 3198 (2006) requires that when promulgating new or revised regulations under section 3633, the Commission 'shall take into account' Federal Trade Commission recommendations about the net economic effects of laws that apply to the United States Postal Service, and subsequent relevant events.'' Order No. 3507 at 3 n.4.

[11] Docket No. RM2007–1, Order No. 43, Establishing Ratemaking Regulations for Market Dominant and Competitive Products, October 29, 2007, at 138.

[12] The methodology for calculating incremental costs approved in Docket No. RM2010–4 is based on a methodology originally proposed in Docket No. R2000–1. When originally proposed, this methodology was applied to all domestic products. *See* Docket No. RM2010–4, Order No. 399, Order Accepting Analytical Principles Used in Periodic Reporting (Proposals Twenty-Two through Twenty-Five), January 27, 2010, at 2–5; *see also* Docket No. R2000–1, Direct Testimony of Nancy R. Kay on Behalf of United States Postal Service, January 12, 2000.

uncodified section 703 would be moot.'' *Id.* The Commission maintains that, notwithstanding section 703's applicability, these conforming changes represent an improved, more complete, or more accurate measure of attributable costs pursuant to section 3622(c) and an improvement in the attribution of costs pursuant to section 3652(e) and therefore reduce potential economic distortions. *Id.*

While the Commission appreciates the Public Representative's comments, its conclusions related to section 703(d)'s applicability in this matter remain unchanged. Therefore, the Commission declines to consider compliance with section 703(d) because these conforming changes are required by law.

c. Postal Service

Comments. The Postal Service notes the same circular reference to incremental costs as indicated by Amazon in proposed § 3015.7(b). Postal Service Comments at 1; *see also* Amazon Comments at 3–4. The Postal Service suggests two alternative versions to proposed § 3015.7(b) that would eliminate the circular reference and would more ''clearly and directly convey[] the intent of the provision.'' Postal Service Comments at 1–2.

The Postal Service also recommends an update to PRC Form CP–01 as part of proposed § 3060.21 by including a ''slightly broader housekeeping change.'' [13] The Postal Service argues competitive market tests should be included in the institutional costs calculation pursuant to 39 U.S.C. 3641(b)(3) and 39 U.S.C. 3633(a)(3), but that in Fiscal Year (FY) 2014 the amounts were too small to ''merit further consideration.'' Postal Service Comments at 2.

However, the Postal Service explains that as part of its FY 2015 Annual Compliance Report (ACR), the amounts had grown larger and it was able to incorporate competitive market test amounts in its contribution target analysis by introducing a new row, Net Contribution Competitive Product Market Tests, into PRC Form CP–01.[14] The Postal Service recommends that the Commission take this opportunity to add the Net Contribution Competitive Product Market Tests row to PRC Form CP–01 in § 3060.21, as the requirements of 39 U.S.C. 3641(b)(3) are ''unlikely to change'' and competitive product market tests have the potential to continue to contribute to institutional costs. Postal Service Comments at 2–3.

Commission analysis. The Commission approves of the update to PRC Form CP–01 as recommended by the Postal Service. While this additional revision to § 3060.21 is not directly related to the Commission's findings in Order No. 3506, the Commission concludes the revision is appropriate as it will result in the Postal Service submitting a more accurate income report. In addition and as noted above, the Commission recognizes the potential confusion related to the references to incremental costs in proposed § 3015.7(b). Revisions to proposed §§ 3015.7(b) and 3060.21 are discussed in chapter IV of this Order.

d. UPS

Comments. UPS asserts the proposed rules are premature as Order No. 3506 is now under review by the Court in Case No. 16–1354 and the instant proceeding was initiated pursuant to that order. UPS Comments at 1; Case No. 16–1354. As a result, UPS requests that the Commission withdraw Order No. 3507 and defer any rule revisions until the Court issues its decision in Case No. 16–1354.[15] Despite its request to defer this proceeding, UPS argues the Postal Service should still be obligated to comply with the directives set forth by the Commission in Order No. 3506.[16]

Commission analysis. The Commission recognizes UPS's concern regarding potential ''procedural complications'' should these rules need to be revised in the future; however, it finds no compelling reason for it to defer this final rulemaking pending the Court's decision in Case No. 16–1354, a proceeding that has not been resolved. Conforming changes to the Code of Federal Regulations (CFR) are necessary in order to comply with Order No. 3506 and require the Postal Service to attribute costs pursuant to that order. In Order No. 3506, based on the information provided, the only costs which the Commission found to have a reliably identified causal relationship to products are incremental costs. This finding expands the scope of cost attribution beyond volume-variable costs and product-specific costs. For these reasons, the Commission declines to defer the instant rulemaking proceeding.

e. Valpak

Comments. Valpak does not specifically support the adoption of the proposed rules but recommends the Commission revise certain CFR rules to require market dominant products to cover their attributable costs. Valpak Comments at 3–5. Valpak cites to a specific discussion in Order No. 3506 and states it ''implies that the average revenue of every product, be it competitive or market dominant, henceforth will (or should) be required by the Commission to cover its incremental cost.'' Valpak Comments at 2 (citing Order No. 3506 at 61). Based on this interpretation, Valpak asserts Order No. 3507 does not comport with Order No. 3506 because in Order No. 3507 the Commission notes attributable cost coverage is one of many factors considered when regulating market dominant products. Valpak Comments at 1–2 (citing Order No. 3507 at 3–4). Valpak argues the discussion in Order No. 3506 necessitates revisions to market dominant product rules that would require market dominant products to cover attributable costs just as competitive products are required to cover their attributable costs.[17] It also states the requirement would protect against the cross-subsidization of competitive products by market dominant products. *Id.* at 5–6.

Commission analysis. The Commission's findings concerning incremental cost attribution across all postal products do not imply that the Commission intended for market dominant products to be *required* to cover their attributable costs. When referring to attributable costs, the definition is the same, *i.e.,* attributable costs are the sum of a product's volume-variable costs, product-specific costs, and those inframarginal costs calculated as part of a product's incremental costs, regardless of whether one is referring to the attributable costs of market dominant products or competitive products. This newly established definition applies to both product types

[13] *Id.* at 2. The Postal Service also notes a numerical inaccuracy with line (8) of proposed § 3060.21 which should read ''Line (8): Difference between Competitive Products total revenues and attributable costs (line 3 less line *7*)'' which will no longer be inaccurate should the Postal Service's other recommended update be included. *Id.;* Order No. 3507 at 10 (emphasis added).

[14] *Id.; see also* Docket No. ACR2015, United States Postal Service FY 2015 Annual Compliance Report, December 29, 2015, at 69 (FY 2015 ACR); Docket No. ACR2015, Library Reference USPS–FY15–39, December 29, 2015.

[15] UPS Comments at 1. UPS notes that the Court's decision in Case No. 16–1354 could have a direct effect on any newly implemented rules and that revising any rules now could ''create unnecessary procedural complications for the Commission and for interested parties.'' *Id.* at 2–3.

[16] UPS Comments at 3 (*i.e.,* the calculation and attribution of product-level incremental costs for products and providing additional information for each cost segment sub-report). *See also* Order No. 3506 at 60–62, 108.

[17] Valpak Comments at 1–5. Valpak recommends revisions to §§ 3010.4 and 3050.1. *Id.* at 3–4.

equally. However, the requirement of attributable cost coverage does not.[18]

In 39 U.S.C. 3622(c)(2), a market dominant product's ability to cover attributable costs is a factor in market dominant product rate regulation. *See* 39 U.S.C. 3622(c)(2). The Commission has long held that should a market dominant product fail to cover its attributable costs, it does not ''compel a finding of noncompliance'' for that product.[19] The Commission's findings in Order No. 3506 do not change prior Commission determinations as to the role of attributable costs. Therefore, the Commission declines to incorporate Valpak's proposed changes to §§ 3010.4 and 3050.1 related to market dominant products and maintains that no rules aside from those discussed in Order No. 3507 require conforming revisions as a result of Order No. 3506.

IV. Changes to Proposed Rules

The Commission adopts final rules that reflect revisions to the proposed rules in response to comments.[20] Mainly, Amazon, the Postal Service, and the Public Representative suggest alternatives to proposed § 3015.7(b) citing a circular reference to incremental costs and readability issues.[21] The Commission finds that the Postal Service's second alternative to proposed § 3015.7(b) provides the most clarity and also improves readability. Accordingly, the Commission revises § 3015.7(b) as set forth in the rules below.

In addition, the Commission finds it appropriate, as an administrative matter, to update PRC Form CP–01 in proposed § 3060.21 and include a new row of expenses titled ''Net Contribution Competitive Products Market Tests'' as recommended by the Postal Service. *See Id.* at 2, 4.

V. Ordering Paragraphs

It is ordered:

1. Parts 3015 and 3060 of title 39, Code of Federal Regulations, are amended as set forth below the signature of this Order, effective 30 days after publication in the **Federal Register**.

2. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

List of Subjects

39 CFR Part 3015

Administrative practice and procedure, Postal service.

39 CFR Part 3060

Administrative practice and procedure, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Commission amends chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3015—REGULATION OF RATES FOR COMPETITIVE PRODUCTS

■ 1. The authority citation of part 3015 continues to read as follows:

Authority: 39 U.S.C. 503; 3633.

■ 2. Amend § 3015.7 by revising paragraphs (a) and (b) to read as follows:

§ 3015.7 Standards for compliance.

* * * * *

(a) Incremental costs will be used to test for cross-subsidies by market dominant products of competitive products. To the extent that incremental cost data are unavailable, the Commission will use the sum of competitive products' volume-variable costs and product-specific costs supplemented to include causally related, group-specific costs to test for cross-subsidies.

(b) Each competitive product must recover its attributable costs as defined in 39 U.S.C. 3631(b). Pursuant to 39 U.S.C. 3631(b), the Commission will calculate a competitive product's attributable costs as the sum of its volume-variable costs, product-specific costs, and those inframarginal costs calculated as part of a competitive product's incremental costs.

* * * * *

PART 3060—ACCOUNTING PRACTICES AND TAX RULES FOR THE THEORETICAL COMPETITIVE PRODUCTS ENTERPRISE

■ 3. The authority citation of part 3060 continues to read as follows:

Authority: 39 U.S.C. 503; 2011, 3633, 3634.

■ 4. Amend § 3060.10 by revising paragraph (b)(1) to read as follows:

§ 3060.10 Costing.

* * * * *

(b) * * *

(1) Attributable costs, including volume-variable costs, product-specific costs, and those inframarginal costs calculated as part of a competitive product's incremental costs; and

* * * * *

■ 5. Amend § 3060.21 by revising table 1 to read as follows:

§ 3060.21 Income report.

* * * * *

TABLE 1—COMPETITIVE PRODUCTS INCOME STATEMENT—PRC FORM CP–01

[$ in 000s]

	FY 20xx	FY 20xx–1	Change from SPLY	Percent change from SPLY
Revenue:	$x,xxx	$x,xxx	$xxx	xx.x
(1) Mail and Services Revenues	xxx	xxx	xx	xx.x
(2) Investment Income	x,xx	x,xxx	xxx	xx.x
(3) Total Competitive Products Revenue				
Expenses:	x,xxx			
(4) Volume-Variable Costs	x,xxx	x,xxx	xxx	xx.x
(5) Product Specific Costs	x,xxx	x,xxx	xxx	xx.x

[18] *Compare* 39 U.S.C. 3622(c)(2) (market dominant products) *and* 39 U.S.C. 3633 (a)(2) (competitive products).

[19] Docket No. ACR2010, FY 2010 Annual Compliance Determination Report, March 29, 2011, at 17 (FY 2010 ACD). Similar views were reiterated by the Commission in other dockets. *See* Docket No. ACR2013, Annual Compliance Determination Report Fiscal Year 2013, March 27, 2014 (FY 2013 ACD) (''The Commission must also consider the 9 objectives and 14 factors in their totality. . . .'' FY 2013 ACD at 57.). *See also* Docket No. ACR2009, FY 2009 Annual Compliance Determination, March 29, 2010 (FY 2009 ACD) (The Commission stated ''[a]s amended by the PAEA, section 3622(c)(2), along with the other factors enumerated, is to be taken into account in the rate-setting process'' and ''[a] finding that a particular factor (or objective) is not satisfied need not result in a determination that a product is not in compliance with the PAEA.'' FY 2009 ACD at 16.).

[20] No comments were received on proposed §§ 3015.7(a) and 3060.10, and the Commission finds no reason to alter the proposed rules.

[21] Amazon Comments at 3; Postal Service Comments at 1; PR Comments at 7.

TABLE 1—COMPETITIVE PRODUCTS INCOME STATEMENT—PRC FORM CP–01—Continued

[$ in 000s]

	FY 20xx	FY 20xx–1	Change from SPLY	Percent change from SPLY
(6) Incremental Inframarginal Costs	x,xxx	x,xxx	xxx	xx.x
(7) Total Competitive Products Attributable Costs	x,xxx	x,xxx	xxx	xx.x
(8) Net Contribution Competitive Products Market Tests	x,xxx	x,xxx	xxx	xx.x
(9) Net Income Before Institutional Cost Contribution	x,xxx	x,xxx	xxx	.....
(10) Required Institutional Cost Contribution	x,xxx	x,xxx	xxx	x.x.x
(11) Net Income (Loss) Before Tax	x,xxx	x,xxx	xxx	xx.x
(12) Assumed Federal Income Tax	x,xxx	x,xxx	xxx	xx.x
(13) Net Income (Loss) After Tax	x,xxx	x,xxx	xxx	xx.x

Line (1): Total revenues from Competitive Products volumes and Ancillary Services.
Line (2): Income provided from investment of surplus Competitive Products revenues.
Line (3): Sum total of revenues from Competitive Products volumes, services, and investments.
Line (4): Total Competitive Products volume-variable costs as shown in the Cost and Revenue Analysis (CRA) report.
Line (5): Total Competitive Products product-specific costs as shown in the CRA report.
Line (6): Inframarginal costs calculated as part of total Competitive Products incremental costs as shown in ACR Library Reference ''Competitive Product Incremental and Group Specific Costs'' (Currently NP10).
Line (7): Sum total of Competitive Products costs (sum of lines 4, 5, and 6).
Line (8) Net Contribution Competitive Products Market Tests as shown in the Annual Compliance Report.
Line (9): Difference between Competitive Products total revenues and attributable costs and Market Tests Contributions (line 3 less line 7 plus line 8).
Line (10): Minimum amount of Institutional cost contribution required under 39 CFR 3015.7 of this chapter.
Line (11): Line 9 less line 10.
Line (12): Total assumed Federal income tax as calculated under 39 CFR 3060.40.
Line (13): Line 11 less line 12.

[FR Doc. 2016–29270 Filed 12–6–16; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2015–0495; FRL–9955–52–Region 6]

Approval and Promulgation of Implementation Plans; Texas; Reasonable Further Progress Plan and Motor Vehicle Emissions Budgets for the Dallas/Fort Worth 2008 Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the Dallas/Fort Worth (DFW) moderate nonattainment area Reasonable Further Progress (RFP) State Implementation Plan (SIP) revision for the 2008 ozone National Ambient Air Quality Standard (NAAQS or standard). EPA is also approving revisions to the 2011 base year emissions inventory for the DFW moderate nonattainment area for the 2008 ozone NAAQS, the 2017 transportation conformity motor vehicle emissions budgets (MVEBs), and the required contingency measures for failure to meet RFP. This action is being taken under the Clean Air Act (CAA).

DATES: This rule is effective on January 6, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2015–0495. All documents in the docket are listed on the *http://www.regulations.gov* Web site. 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: Wendy Jacques, 214–665–7395, *jacques.wendy@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 September 20, 2016 proposal (81 FR 64372). In that document we proposed to approve the DFW RFP SIP revision for the 2008 ozone standard submitted by the State of Texas. EPA also proposed to approve revisions to the 2011 base year emissions inventory for the DFW moderate nonattainment area for the 2008 ozone NAAQS, the 2017 transportation conformity motor vehicle emissions budgets (MVEBs), and the required contingency measures for failure to meet RFP. We did not receive any comments regarding our proposal.

II. Final Action

We are approving the DFW RFP SIP revision for the 2008 ozone standard that was submitted on July 10, 2015 and supplemented on April 22, 2016. We are approving the revised base year emission inventory, the RFP plan, the 2017 MVEBs and the required contingency measures for failure to meet RFP. The 2017 MVEBs are listed in Table 1.

TABLE 1—DFW RFP MVEBS

[Tons per day]

Year	NO_X	VOC
2017	148.36	77.18

This action is being taken under section 110 of the CAA.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 6, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: December 1, 2016.

Ron Curry,

Regional Administrator, Region 6.

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 SS—Texas

■ 2. In § 52.2270 (e), the second table titled ''EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the Texas SIP'' is amended by adding a new entry at the end for ''DFW Reasonable Further Progress SIP Revision for the 2008 Ozone Standard'' to read as follows.

§ 52.2270 Identification of plan.

* * * * *

(e) * * *

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

Name of SIP provision	Applicable geographic or non-attainment area	State submittal/ effective date	EPA approval date	Comments
*	*	*	*	*
DFW Reasonable Further Progress (RFP) Plan, RFP Contingency Measures, RFP Motor Vehicle Emission Budgets for 2017, and Revised 2011 Base Year Emissions Inventory for the 2008 Ozone NAAQS.	Collin, Dallas, Denton, Ellis, Johnson, Kaufman, Parker, Rockwall, Tarrant and Wise Counties, TX.	7/10/2015	12/7/2016 [Insert **Federal Register** citation].	Supplement submitted on April 22, 2016.

[FR Doc. 2016–29274 Filed 12–6–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 435

[EPA–HQ–OW–2014–0598; FRL–9956–05–OW]

RIN 2040–AF68

Effluent Limitations Guidelines and Standards for the Oil and Gas Extraction Point Source Category—Implementation Date Extension

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to extend the implementation deadline for certain facilities subject to the final rule establishing pretreatment standards under the Clean Water Act (CWA) for discharges of pollutants into publicly owned treatment works (POTWs) from onshore unconventional oil and gas (UOG) extraction facilities.

DATES: The final rule is effective December 7, 2016. In accordance with 40 CFR part 23, this regulation shall be considered issued for purposes of judicial review at 1 p.m. Eastern time on December 21, 2016. Under section 509(b)(1) of the CWA, judicial review of this regulation can be had only by filing a petition for review in the U.S. Court of Appeals within 120 days after the regulation is considered issued for purposes of judicial review. Under section 509(b)(2), the requirements in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2014–0598. All documents in the docket are listed on the *https://www.regulations.gov* Web site. 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. This material can be viewed at the Water Docket in the EPA Docket Center, EPA/DC, EPA West William Jefferson Clinton Bldg,. Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading room is 202–566–1744, and the telephone number for the Water Docket is 202–566–2426. Publicly available docket materials are available electronically through *http://www.regulations.gov.* A detailed record index, organized by subject, is available on EPA's Web site at *https://www.epa.gov/eg/unconventional-oil-and-gas-extraction-effluent-guidelines.*

FOR FURTHER INFORMATION CONTACT: For more information, see the EPA's Web site: *https://www.epa.gov/eg/unconventional-oil-and-gas-extraction-effluent-guidelines.* For technical information, contact Karen Milam, Engineering and Analysis Division (4303T), Office of Water, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone: 202–566–1915; email: *milam.karen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

Entities potentially regulated by this final action include:

Category	Example of regulated entity	North American Industry Classification System (NAICS) Code
Industry	Crude Petroleum and Natural Gas Extraction	211111
Industry	Natural Gas Liquid Extraction	211112

II. Supplementary Information

A. Background

The EPA promulgated revisions to the Effluent Guidelines and Standards for the Oil and Gas Extraction Point Source Category which established pretreatment standards for onshore UOG extraction facilities (81 FR 41845, June 28, 2016). This final pretreatment standards rule prohibited the discharge of pollutants in UOG extraction wastewater to POTWs, and established an effective date of August 29, 2016. In the preamble to the final pretreatment standards rule, the EPA indicated that because UOG facilities were currently meeting this zero discharge requirement, the implementation deadline for these pretreatment standards would be the same as the effective date of the final rule. After promulgation of the final rule, the EPA received two letters indicating that there are likely facilities discharging UOG wastewater to POTWs; this was new information to the EPA.

In light of this post-promulgation information, on September 30, 2016 (81 FR 67266, September 30, 2016), the EPA published a proposed rule to extend the compliance date to August 29, 2019, for existing sources that were lawfully discharging UOG wastewater to POTWs on or between the date of the **Federal Register** Notice of the proposed UOG pretreatment standards rule (80 FR 18557, April 17, 2015) and the date of the **Federal Register** action of the final UOG pretreatment standards rule (81 FR 41845, June 28, 2016). For purposes of this final rule, compliance date and implementation date are used interchangeably.

B. Description of EPA's Action

Based on the post-promulgation information submitted to the EPA suggesting that there are likely facilities subject to the final UOG pretreatment standards rule that are currently discharging UOG wastewater to POTWs, the EPA is extending the compliance date for existing sources that were lawfully discharging to POTWs on or between April 7, 2015 and June 28, 2016, to three years from the effective date of the rule—to August 29, 2019. This final rule does not change the compliance date for all other facilities subject to the final onshore UOG extraction pretreatment standards rule.

C. Response to Comments

Comments received in response to the proposed rulemaking supported the extension of the compliance date for these facilities. The EPA did not receive any comments that opposed or otherwise questioned the appropriateness of the extension of the compliance date. The EPA did, however, receive comments regarding the applicability of the underlying pretreatment standards rule. Specifically, these comments disagreed with the definition of ''unconventional'' in the final UOG rule, arguing that the definition was ''overly broad'' or ''arbitrary,'' and suggested alternative definitions of ''unconventional'' that

may exclude certain operators in Pennsylvania that have been sending their wastewater to POTWs. These comments are outside the scope of the proposed rule, which was specifically limited to the extension of the compliance date. *See* 81 FR 67267; September, 30, 2016 (''EPA will not consider any comment submitted on the proposed rule published today on any topic other than the appropriateness of an extension of the compliance date; any other comments will be considered outside the scope of this rulemaking.''). As clarified in the preamble to the proposed rulemaking, the rule simply extends the implementation deadline for certain facilities subject to the underlying final UOG pretreatment standard rule and does not otherwise amend the final pretreatment standards rule in any way. *See* 81 FR 67266, 67267; September 30, 2016 (incorporating rationale set forth in direct final rule at 81 FR 67191, 67192; September 30, 2016). Therefore, the EPA maintains that comments regarding the applicability of the underlying pretreatment standards rule are outside the scope of the proposed rule. Any such challenges were required to be raised with respect to the underlying pretreatment standards rule, and not with this final rule, which is limited to the extension of the compliance date.

The EPA's extension of the compliance date by three years is reasonable, as acknowledged by industry commenters on the direct final rule. *See, e.g.,* Comments from Pennsylvania Independent Oil and Gas Association (finding the three year extension to be ''a reasonable, measured and appropriate accommodation.''). As noted in the proposed rule, this is consistent with the EPA's General Pretreatment regulations, which require existing sources to meet categorical pretreatment standards within three years of the effective date of such standards, unless a shorter compliance time is specified therein. 40 CFR 403.6(b). Although commenters expressed generalized concerns about adverse impacts on facilities that have been sending UOG wastewater to POTWs, these generalized concerns are not sufficient to undermine the reasonableness of a three year timeframe for these facilities to meet the pretreatment standard—particularly when the rulemaking record for the EPA's final UOG pretreatment standard rule demonstrates that other similarly-situated operators are currently meeting the zero discharge pretreatment standard today. EPA did not receive any comments or data attempting to explain why the facilities subject to this final rule would need longer than three years in order to meet the requirements that are currently being met by the vast majority of the industry.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this action is not a ''significant regulatory action'' and is therefore not subject to OMB review. With respect to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this action will not have a significant economic impact on a substantial number of small entities—as this direct final relieves regulatory burden by extending the compliance date for any businesses (including small businesses) that were discharging UOG wastewater to POTWs at the time of issuance of the pretreatment standard. For the Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4), this action does not significantly or uniquely affect small governments. The action imposes no incremental enforceable duty on any state, local or tribal governments or the private sector. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (65 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Congressional Review Act

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 435

Environmental protection, Pretreatment, Unconventional oil and gas extraction, Waste treatment and disposal, Water pollution control.

Dated: November 28, 2016.

Gina McCarthy,

Administrator.

Therefore, 40 CFR part 435 is amended as follows:

PART 435—OIL AND GAS EXTRACTION POINT SOURCE CATEGORY

■ 1. The authority citation for part 435 continues to read as follows:

Authority: 33 U.S.C. 1251, 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

Subpart C—Onshore Subcategory

■ 2. Amend § 435.33 by adding paragraph (a)(3) to read as follows:

§ 435.33 Pretreatment standards for existing sources (PSES).

(a) * * *

(3) *Compliance deadline for existing sources.* Existing sources discharging into publicly owned treatment works on or between April 7, 2015 and June 28, 2016, shall comply with the PSES by August 29, 2019. All other existing sources shall comply by August 29, 2016.

* * * * *

[FR Doc. 2016–29338 Filed 12–6–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 207

[Docket No. FRA–2016–0107, Notice No. 1]

RIN 2130–AC62

Railroad Police Officers

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This rule amends FRA's regulations on railroad police officers to implement certain provisions of the Fixing America's Surface Transportation

(FAST) Act. Consistent with the FAST Act, FRA is amending its regulations to allow: Railroads to hire contractors as railroad police officers; railroad police officers to transfer from one state to another without immediately needing to be commissioned or certified in the new state; and a state to recognize an officer's training at another state's recognized police academy or at a Federal law enforcement training center as meeting the state's basic police officer certification or commissioning requirements.

DATES: This final rule is effective February 6, 2017.

FOR FURTHER INFORMATION CONTACT: Gareth Rosenau, Office of Chief Counsel, Federal Railroad Administration, Mail Stop 10, Room W31–316, 1200 New Jersey Avenue SE., Washington, DC 20590 (telephone: 202–493–6054).

SUPPLEMENTARY INFORMATION:

I. Background

Prior to enactment of the FAST Act (Pub. L. 114–94 (Dec. 4, 2015)), 49 U.S.C. 28101 (Section 28101) authorized railroad employees commissioned or certified as police officers by any state to enforce, consistent with DOT regulations, the laws of any state where the railroad police officer's employer owns property to protect railroad property, personnel, passengers, and cargo. Section 28101 did not allow railroads to hire contractor railroad police officers or allow a railroad police officer to transfer from one state to another unless that officer was immediately commissioned or certified in the new state. Section 28101 also did not address training railroad police officers, except general references to the certification or commissioning of the officers under state law. FRA's regulations at 49 CFR part 207 implement Section 28101.

FAST Act Section 11412(b) (Section 11412) revised Section 28101 to allow: (1) Railroads to hire contractors as railroad police officers; (2) railroad police officers to transfer from one state to another without immediately needing to be commissioned or certified in the new state; and (3) a state to recognize an officer's training at another state's recognized police academy or a Federal law enforcement training center meets the state's basic police officer certification or commissioning requirements.[1]

Section 11412 also requires the Secretary of Transportation (Secretary) to, within one year of enactment of the FAST Act, revise part 207 consistent with Section 11412. The authority to carry out this mandate is delegated to FRA. *See* 49 CFR 1.89(a). In issuing this final rule, neither the Secretary nor FRA is exercising any discretion in modifying part 207. Instead, this final rule merely incorporates the new Section 11412 statutory language into existing part 207 and, in certain instances, updates part 207 to ensure consistent application of the regulation, as modified by the FAST Act.

II. The FAST Act's Specific Mandates Addressed in This Final Rule

The FAST Act made three substantive revisions to existing Section 28101. First, the FAST Act revised Section 28101 paragraphs (a) and (b) to allow railroad police officers to be either direct employees of a railroad or contractors to a railroad (prior to the FAST Act, Section 28101 required railroad police officers to be ''employed by'' a railroad). Specifically, the FAST Act amended Section 28101(a) (the general authorizing provision for railroad police officers) to specify railroad police officers may be ''directly employed by or contracted by'' railroads. This change allows railroads to not only directly employ railroad police officers, but also to hire contractors as railroad police officers. In Section 28101(b) (which allows a railroad police officer to be temporarily assigned to assist a second railroad), the FAST Act revised the words ''employed by'' to ''directly employed by or contracted by'' and specified that a railroad police officer assisting a second railroad is an employee ''or agent, as applicable'' of the second railroad carrier.

Second, the FAST Act added a new paragraph (c) to Section 28101 addressing the transfer of railroad police officers from one state of employment or residence to a state other than the one where he or she is commissioned. New paragraph (c) provides a one year interim period for the officer to become commissioned in the new state, while retaining authority to enforce laws in the new state under Section 28101.

Third, the FAST Act added a new paragraph (d) to Section 28101 specifically allowing a state to allow a railroad police officer's training at another state's recognized police academy or at a Federal law enforcement training center to meet the state's basic police officer certification or commissioning requirements.

III. Justification for Final Rule

FRA is proceeding directly to a final rule in this proceeding because it finds, for good cause, notice and public comment is unnecessary because the public would not benefit from such notice. *See* 5 U.S.C. 553(b)(B). In this rule, FRA is merely incorporating the new statutory language of the FAST Act into existing part 207, and, in doing so, is exercising no discretion. *See, e.g., Komjathy* v. *National Transp. Safety Bd.,* 832 F.2d 1294 (D.C. Cir. 1987), cert. denied, *Komjathy* v. *Administrator, Federal Aviation Admin.,* 486 U.S. 1057 (1988).

IV. Section-by-Section Analysis

Section 207.1 Application

Existing § 207.1 states part 207 applies to ''all railroads,'' as defined in section 202(e) of the Federal Railroad Safety Act of 1970. FRA is updating this section to accurately reflect the current statutory cite for the term ''railroad.'' 49 U.S.C. 20103. This only updates an outdated statutory citation and is not a substantive amendment.

Section 207.2 Definitions

Existing paragraph (a) of § 207.2 defines ''railroad police officer'' as a ''peace officer who is commissioned in his or her state of legal residence or state of primary employment and employed by a railroad to enforce state laws for the protection of railroad property, personnel, passengers, and/or cargo.'' Consistent with the mandate of Section 11412, this rule revises this definition by clarifying that term includes peace officers ''directly employed by'' or ''contracted by'' a railroad.

Section 207.3 Designation and Commissioning

Existing paragraph (b) of § 207.3 requires railroad police officers to be commissioned by the officer's state of legal residence or the officer's state of primary employment. Consistent with Section 11412's new provision providing for a one year interim period for an officer transferring from one state of employment or residence to another to become commissioned or certified in the new state, FRA is revising this paragraph to except railroad police officers from this commissioning requirement during such an interim period by referencing new § 207.6 (discussed below).

[1] Section 11412 of the FAST Act also contained provisions modifying 49 U.S.C. 24305(e) (authorizing Amtrak to employ railroad police officers) and 18 U.S.C. 922(z)(2)(B) (excepting railroad police officers from certain restrictions related to handguns). These provisions are self-executing and require no revision to part 207 or any other FRA regulation.

Section 207.6 Transfers

Consistent with new Section 28101(c), FRA is adding new § 207.6 to address transferring railroad police officers from one state of employment or residence to a state other than the one where he or she is commissioned. Section 207.6(a) provides that if a railroad police officer certified or commissioned as a police officer under the laws of a state or jurisdiction transfers primary employment or residence from the certifying or commissioning state to another state or jurisdiction, then the railroad police officer must apply to be certified or commissioned as a police officer under the laws of the state of new primary employment or residence not later than one year after the date of transfer. Section 207.6(b) provides that during the period beginning on the date of transfer and ending one year after the date of transfer, a railroad police officer certified or commissioned as a police officer under the laws of a state may enforce the laws of the new state or jurisdiction in which the railroad police officer resides, to the same extent as provided in existing § 207.5(a) governing the authority of railroad police officers in states where the officer is not commissioned or certified.

Section 207.7 Training

Consistent with new Section 28101, FRA is adding new § 207.7 specifically allowing a state to recognize a railroad police officer's training at another state's recognized police academy or at a Federal law enforcement training center meets the state's basic police officer certification or commissioning requirements. Tracking paragraph (d)(1) of Section 28101, paragraph (a) of new § 207.7 specifically allows states to recognize its basic police officer certification or commissioning requirements for qualification as a railroad police officer are met by any individual who successfully completes a program at another state's state-recognized police training academy or a Federal law enforcement training center and who is certified or commissioned as a police officer by that other state. Tracking paragraph (d)(2) of Section 28101, paragraph (b) of new § 207.7 explains the rule may not be construed to supersede or affect any state training requirements related to criminal law, civil procedure, motor vehicle code, any other state law, or state-mandated comparative or annual in-service training academy or Federal law enforcement training center.

V. Regulatory Impact and Notices

A. Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures

FRA evaluated this final rule under existing policies and procedures and determined it is non-significant, under both Executive Orders 12866 and 13563, and DOT policies and procedures. *See* 44 FR 11034, Feb. 26, 1979. Because FRA determined the anticipated costs from this final rule are *de minimis,* FRA did not prepare a separate regulatory impact assessment document. Instead, FRA summarized its assessment of the cost and benefit expected to result from implementation of this final rule here.

First, FRA found this final rule will not create any additional burden on any entities. Thus, we do not expect the rule to result in any costs, either quantifiable or non-quantifiable, as the rule does not create any additional requirements entities must follow.

Second, FRA found the final rule provides benefits to entities and benefits to workers from the three provisions allowing: (1) Railroads to hire contractor police officers; (2) railroad police officers to transfer from one state to another without immediately needing to be commissioned or certified in the new state; and (3) a state to recognize an officer's training at another state's recognized police academy or at a Federal law enforcement training center meets the state's basic police officer certification or commissioning requirements.

Providing entities with the ability to employ contractor police officers more easily allows entities to adjust employment rolls based upon their business needs. Providing flexibility for railroad police officers to transfer from one state to another allows for increased mobility of railroad police officers to meet interstate business needs. Increased interstate worker mobility addresses the current geographic immobility of railroad police officers caused by existing law that typically requires railroad police officers to be commissioned within their states of residence or primary employment. Similar to how allowing railroads to employ contractor police officers will lead to increased interstate worker mobility, allowing states to recognize an officer's training completed within another state or at a Federal law enforcement training center as meeting that state's basic police officer certification or commissioning requirements will likewise increase the interstate mobility of railroad police officers.

Thus, FRA concludes this final rule will result in several non-quantifiable benefits that allow railroads to more efficiently allocate the railroad police officer workforce based upon employment needs. Therefore, the final rule benefits workers because there is increased worker mobility, and the final rule benefits railroads, because of the increased flexibility and efficiency they have to allocate railroad police officers.

It is important to note the total number of railroad police officers is not expected to change as a result of this final rule. However, this final rule may result in a more stable labor market for railroad police officers, with a lower employment turnover rate, since railroad police officers can more easily relocate.

B. Regulatory Flexibility Act and Executive Order 13272; Certification

FRA developed this final rule under Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) to ensure potential impacts of rules on small entities are properly considered.

The Regulatory Flexibility Act requires an agency to review regulations to assess their impact on small entities. An agency must conduct a regulatory flexibility analysis unless it determines and certifies that a rule is not expected to have a significant economic impact on a substantial number of small entities.

This final rule will apply to all entities employing or contracting for railroad police officers. Because the final rule does not impose any substantive requirements on regulated entities (either large or small), FRA estimates this rule imposes no costs on regulated entities. Thus, because this final rule does not create any costs, it will not result in greater costs per employee for small entities as compared to large entities.

FRA estimates there are fewer than 5 railroads that are both small entities for purposes of this analysis, and that employ or contract for railroad police officers. Moreover, because there are no costs associated with this final rule, the economic impact on these small entities is not significant.

1. Description of Regulated Entities and Impacts

The ''universe'' of entities under consideration includes only those small entities that can reasonably be expected to be directly affected by this final rule. The only small entities potentially

affected by this final rule are small railroads that employ or contract for railroad police officers.

''Small entity'' is defined in 5 U.S.C. 601 (Section 601). Section 601(6) defines ''small entity'' as having ''the same meaning as the terms 'small business', 'small organization' and 'small governmental jurisdiction' '' as defined by Section 601. Section 601(3) defines ''small business'' as having the same meaning as ''small business concern'' under Section 3 of the Small Business Act. Section 601(4) defines ''small organization'' as ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Section 601(5) defines ''small governmental jurisdiction'' as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.''

The U.S. Small Business Administration (SBA) stipulates ''size standards'' for small entities. It provides that the largest a for-profit railroad business firm may be (and still be classified as a ''small entity'') is 1,500 employees for ''Line-Haul Operating Railroads'' and 500 employees for ''Short-Line Operating Railroads.''[2] Additionally, 5 U.S.C. 601(5) defines as ''small entities'' governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000.

Federal agencies may adopt their own size standards for small entities in consultation with SBA and in conjunction with public comment. Under that authority, FRA has published a final statement of agency policy formally establishing for FRA's regulatory purposes ''small entities'' or ''small businesses'' as railroads, contractors, and hazardous materials shippers that meet the revenue requirements of a Class III railroad as set forth in 49 CFR 1201.1–1 (which is $20 million or less in inflation-adjusted annual revenues, and commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less).[3] FRA used this definition for this rulemaking.

FRA could not exactly quantify the number of entities that could be impacted by this final rule if there was a burden. However, evidence exists that, because of resource constraints, most Class III railroads (small entities) do not employ railroad police officers. *See ASLRRA Aims to Help 560 Roads Address Hazmat Car Security,* Progressive Railroading, April 2009. Nevertheless, there may be commuter railroads or small governmental jurisdictions that serve populations of 50,000 or less that would be considered small entities and would be impacted by this final rule with no associated burden. Although there is no associated burden, FRA conservatively estimates this final rule will impact approximately 30 railroads, five of which meet FRA's definition of a ''small entity.''

There are approximately 695 small railroads (as defined by revenue size). Class III railroads do not report to the STB, and the precise number of Class III railroads is difficult to ascertain due to conflicting definitions, conglomerates, and even seasonal operations. Potentially, all small railroads could be impacted by this final regulation, but there is no reason to believe that any additional small railroads are likely to employ or contract for railroad police officers.

Significant Economic Impact Criteria

Previously, FRA sampled small railroads and found that revenue averaged approximately $4.7 million (not discounted) in 2006. One percent of that average annual revenue per small railroad is $47,000. FRA realizes that some railroads will have lower revenue than $4.7 million. FRA estimates that this rule will not result in any additional expense to small railroads over the next ten years, as the final rule does not require entities to comply with anything. That is, while this final rule provides entities with relaxed constraints on how to employ railroad police officers, this final rule does not introduce any new requirements itself. Therefore, FRA concludes there is no expected burden for this final rule so it will not have a significant impact on the financial position of small entities, or on the small entity segment of the railroad industry as a whole.

Substantial Number Criteria

Because this final rule does not contain any provision requiring action on the part of entities, either large or small, this final rule will not impact a substantial number of small entities.

2. Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), FRA certifies this final rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements in this final rule are being submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*. The sections that contain the new and current information collection requirements are duly designated, and the estimated time to fulfill each requirement is as follows:

CFR Section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
207.4—RR Notice to State Officials—Written notice of RR police officer's commission to each state in which the RR police officer shall protect the railroad's property, personnel, passengers, and cargo.	763 railroads	35 notices	5 hours	175
—RR Copy of Written Notices to State Officials.	763 railroads	35 records/copies	10 minutes	6
207.6—Transfers—Application by RR police officer for new state certification/commission when transferring primary employment or residence from one State to Another (New Provision).	763 railroads	30 state certification applications.	1 hour	30

[2] ''Table of Size Standards,'' U.S. Small Business Administration, Jan. 31, 1996, 13 CFR part 121.

[3] *See* 49 CFR part 209, appendix C.

CFR Section/subject	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
207.7—Training—RR police officer training successful completion at a state's police academy training program in one state recognized by other state (New Provision).	763 railroads	30 trained RR police officers.	40 hours	1,200

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. For information or a copy of the unchanged paperwork package submitted to OMB, contact Mr. Robert Brogan at 202–493–6292 or Ms. Kimberly Toone at 202–493–6132 or via email at the following addresses: *Robert.Brogan@dot.gov; Kimberly.Toone@dot.gov.*

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to the Office of Management and Budget at the following address: *oira_submissions@omb.eop.gov*

OMB is required to make a decision concerning the collection of information requirements contained in this final rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

FRA cannot impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of the final rule. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

D. Federalism

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by state and local governments, or the agency consults with state and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts state law, the agency seeks to consult with state and local officials in the process of developing the regulation.

This final rule has been analyzed consistent with the principles and criteria in Executive Order 13132. FRA has determined this rule does not have 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 rule does not impose substantial direct compliance costs on state and local governments. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

E. Environmental Impact

FRA has evaluated this final rule consistent with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), other environmental statutes, related regulatory requirements, and its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999). FRA has determined this final rule is categorically excluded from detailed environmental review under section 4(c)(20) of FRA's NEPA Procedures, ''Promulgation of railroad safety rules and policy statements that do not result in significantly increased emissions of air or water pollutants or noise or increased traffic congestion in any mode of transportation.'' *See* 64 FR 28547, May 26, 1999. Categorical exclusions (CEs) are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4.

In analyzing the applicability of a CE, the agency must also consider whether extraordinary circumstances are present that would warrant a more detailed environmental review through the preparation of an EA or EIS. *Id.* Consistent with section 4(c) and (e) of FRA's Procedures, the agency has further concluded no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. The purpose of this rulemaking is to conform FRA's regulation on railroad police officers to the statutory provisions of Section 11412 of the FAST Act which provide additional flexibility for railroads to hire, employ, and train railroad police officers than previously provided. FRA does not anticipate any environmental impacts from this requirement and finds that there are no extraordinary circumstances present in connection with this final rule.

F. Executive Order 13175 (Tribal Consultation)

FRA has evaluated this final rule consistent with the principles and criteria in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, dated November 6, 2000. The final rule would not have a substantial direct effect on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal laws. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply, and a tribal summary impact statement is not required.

G. 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) (91 FR 27534, May 10, 2012) require DOT agencies to achieve environmental justice 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 populations and low-income populations. The DOT Order instructs DOT agencies to address compliance with Executive Order 12898 and requirements within the DOT Order in rulemaking activities, as appropriate. FRA has evaluated this rule under Executive Order 12898 and the DOT Order and determined it would not cause disproportionately high and adverse human health and environmental effects on minority populations or low-income populations.

H. Unfunded Mandates Reform Act of 1995

Under Section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that

> before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement

detailing the effect on state, local, and tribal governments and the private sector. This final rule will not result in the expenditure, in the aggregate, of $100,000,000 or more (as adjusted annually for inflation) in any one year, and thus preparation of such a statement is not required.

I. Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355, May 22, 2001. Under the Executive Order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this final rule consistent with Executive Order 13211. FRA has determined this final rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Consequently, FRA has determined this final rule is not a ''significant energy action'' within the meaning of Executive Order 13211.

J. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39, 19 U.S.C. 2501 *et seq.*) prohibits Federal agencies from engaging in any standards setting or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

FRA has assessed the potential effect of this final rule on foreign commerce and believes its requirements are consistent with the Trade Agreements Act of 1979. The requirements imposed relate to safety standards, which, as noted, are not considered unnecessary obstacles to trade.

K. Privacy Act

Consistent 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.*

List of Subjects in 49 CFR Part 207

Law enforcement, Law enforcement officers, Railroad employees, Railroad safety.

The Rule

In consideration of the foregoing, FRA amends chapter II, subtitle B of title 49, Code of Federal Regulations as follows:

PART 207—[AMENDED]

■ 1. The authority citation for part 207 continues to read as follows:

Authority: 49 U.S.C. 28101; 49 CFR 1.89.

■ 2. Revise § 207.1 to read as follows:

§ 207.1 Application.

This part applies to all railroads as defined in 49 U.S.C. 20103.

■ 3. Revise § 207.2(a) to read as follows:

§ 207.2 Definitions.

* * * * *

(a) *Railroad police officer* means a peace officer who is commissioned in his or her state of legal residence or state of primary employment and directly employed by or contracted by a railroad to enforce state laws for the protection of railroad property, personnel, passengers, and/or cargo.

* * * * *

■ 4. Revise § 207.3(b) to read as follows:

§ 207.3 Designation and commissioning.

* * * * *

(b) Except as provided by § 207.6, the designated railroad police officer shall be commissioned by the railroad police officer's state of legal residence or the railroad police officer's state of primary employment.

■ 5. Add § 207.6 to read as follows:

§ 207.6 Transfers.

(a) *General.* If a railroad police officer certified or commissioned as a police officer under the laws of a state or jurisdiction transfers primary employment or residence from the certifying or commissioning state to another state or jurisdiction, then the railroad police officer must apply to be certified or commissioned as a police officer under the laws of the state of new primary employment or residence not later than one (1) year after the date of transfer.

(b) *Interim period.* During the period beginning on the date of transfer and ending one year after the date of transfer, a railroad police officer certified or commissioned as a police officer under the laws of a state may enforce the laws of the new state or jurisdiction in which the railroad police officer resides, to the same extent as provided in § 207.5(a).

■ 6. Add § 207.7 to read as follows:

§ 207.7 Training.

(a) A state may consider an individual to have met that state's basic police officer certification or commissioning requirements for qualification as a railroad police officer under this section if that individual:

(1) Has successfully completed a program at a state-recognized police training academy in another state or at a Federal law enforcement training center; and

(2) Is certified or commissioned as a police officer by the other state.

(b) Nothing in this section shall be construed as superseding or affecting any state training requirements related to criminal law, civil procedure, motor vehicle code, any other state law, or state-mandated comparative or annual in-service training academy or Federal law enforcement training center.

Issued in Washington, DC, on December 1, 2016.

Amitabha Bose,

Acting Administrator.

[FR Doc. 2016–29256 Filed 12–6–16; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 225

RIN 2130–AC58

Update to Email Address for the Electronic Submission via the Internet of Certain Accident/Incident Reports

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule updates FRA's accident/incident reporting regulations to provide the current electronic mail address railroads must use to electronically submit to FRA certain accident/incident report forms.

DATES: Effective: December 7, 2016.

FOR FURTHER INFORMATION CONTACT: Kebo Chen, Staff Director, U.S. Department of Transportation, Federal Railroad Administration, Office of Safety Analysis, RRS–22, Mail Stop 25, West Building 3rd Floor, Room W33–314, 1200 New Jersey Ave. SE., Washington, DC 20590 (telephone 202–493–6079); or Gahan Christenson, Trial Attorney, U.S. Department of Transportation, Federal Railroad Administration, Office of Chief Counsel, RCC–10, Mail Stop 10, West Building 3rd Floor, Room W33–435, 1200 New Jersey Ave. SE., Washington, DC 20590 (telephone 202–493–1381).

SUPPLEMENTARY INFORMATION: This rule updates the electronic mail (email) address provided in 49 CFR part 225 for railroads to electronically submit certain FRA accident/incident report forms.[1] Part 225 references the FRA email address in two places: Paragraph (c) of § 225.27 and paragraph (c)(1) of § 225.37. Those paragraphs direct railroads to submit the specified forms to the following email address: *aireports@frasafety.net.* This FRA email address is out of date and no longer functional. Accordingly, in this rule FRA is updating the email address referenced in paragraph (c) of § 225.27 and paragraph (c)(1) of § 225.37 to the current email address where FRA can receive these reports. The current email address is: *RsisAiReports@dot.gov.*

Starting in 2013, FRA informed railroad reporting officers of the change in the email address in §§ 225.27 and 225.37 and started transitioning to the new *RsisAiReports@dot.gov* email address. FRA established the *RsisAiReports@dot.gov* email address to avoid increased costs associated with the previous email address in the regulations. Until December 31, 2015, FRA accepted emailed accident/incident report forms at the email address in part 225 (*aireports@frasafety.net*) and at *RsisAiReports@dot.gov,* but the *aireports@frasafety.net* email address no longer functions.

This rule only updates the email address in the regulation and makes no other changes to part 225. FRA is issuing this final rule without providing an opportunity for prior to public notice and comment as the Administrative Procedure Act (APA) normally requires. *See* 5 U.S.C. 553. The APA authorizes agencies to dispense with certain notice and comment procedures if the agency finds for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. *See* 5 U.S.C. 553(b)(3)(B). Because this final rule makes no substantive amendment to FRA's regulations and only changes the email address for railroads to submit to FRA certain already required documents, FRA finds, for good cause, that notice and public comment is unnecessary, because the public would not benefit from such notice. Moreover, The scope of this regulatory change is very limited; FRA is merely replacing an outdated email address with a current email address.

Regulatory Evaluation

Executive Orders 12866 and 13563 and DOT Regulatory Policies and Procedures

FRA evaluated this final rule under existing policies and procedures and determined it to be a non-significant regulatory action under both Executive Orders 12866 and 13563 and DOT policies and procedures. *See* 44 FR 11034, Feb. 26, 1979. This final rule only updates the email address used by railroads to report certain accident/incident forms to FRA, and makes no substantive changes to part 225's reporting requirements. This rule is necessary because the current email address is out of date and no longer accepts accident/incident report forms. Over the past three years, FRA has repeatedly notified railroads of the new email address that should be used for submitting accident/incident report forms. Consequently, most railroads already use the new email address referenced in this rule, but some do not and will need to do so under this final rule. These railroads will incur a minor administrative burden to make note of the new email address and revise their contact lists accordingly, in comparison to no change in the email address used to submit accident/incident report forms to FRA.

The administrative burden to update the email address will depend on how the railroads submit accident/incident report forms to FRA. In general, railroads use the email address in two ways to submit accident/incident report forms. First, a railroad may manually enter the email address into its email program or electronic device (such as a multi-function printer) each time the railroad submits an accident/incident report form to FRA. In this case, substituting the new email address for the old one would present no additional burden because the railroad would have had to enter an email address regardless. Furthermore, if occasionally updating email addresses is a regular part of a railroad reporting officer's duties (the employee most likely to submit accident/incident report forms to FRA), the burden of updating the email address is already taken into account. The railroad employee would only need to take note of the new email address, requiring a minimal amount of time.

Second, a railroad may use an automated system to submit accident/incident report forms to FRA. In such a system, the reporting officer would need to update, save and/or compile, and check for errors when using the new email address (such as entering in the email address wrong). These steps are standardized, and again, would require minimal time to update one email address. In addition, whether email addresses are entered manually, or stored in an automated system, the email address would only need to be updated once. Thus, given the small amount of time needed to revise the current email address to the new one, and one-time occurrence of the task, the costs associated with this change will be minimal.

[1] FRA is not simultaneously updating the email address in the FRA Guide for Preparing Accident/Incident Reports (Guide) because this final rule and updates on FRA's Web site, in addition to communication between FRA and individual railroads, makes it unnecessary to revise the Guide at this time.

In sum, this final rule makes no substantive changes to part 225's reporting requirements. The rule only makes an administrative change to facilitate railroads submission of accident/incident forms to FRA. Thus, the rule imposes no significant additional costs, and creates no new significant benefits and FRA has determined further analysis under Executive Orders 12866, 13563 or DOT policies and procedures is not necessary.

Regulatory Flexibility Act and Executive Order 13272

FRA developed this rule under Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) to ensure potential impacts of rules on small entities are properly considered.

The Regulatory Flexibility Act of 1980 (RFA) requires an agency to review regulations to assess their impact on small entities. An agency must conduct a regulatory flexibility analysis unless it determines and certifies that a rule is not expected to have a significant economic impact on a substantial number of small entities.

This final rule simply updates an email address railroads use to electronically submit to FRA certain accident/incident report forms. This rule does not contain any new substantive regulatory requirements. As a result, this rule will impose no new compliance costs on small entities other than those minimal potential costs outlined above in the Regulatory Evaluation section. Under the RFA, the Administrator of FRA certifies this final rule will have no significant economic impact on a substantial number of small entities.

Furthermore, FRA has determined the RFA does not apply to this rulemaking because FRA is not publishing a proposed rule in this proceeding. Given the minor change to replace an outdated email address with a current email address and FRA's finding that notice and public comment is unnecessary and would serve no public benefit, per guidance from the Small Business Administration, the RFA does not apply. *See A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,* Small Business Administration, Office of Advocacy (May 2012, p.55).

Paperwork Reduction Act

There are no new or additional information collection requirements associated with this final rule. FRA's collection of accident/incident reporting and recordkeeping information is currently approved under OMB No. 2130–0500. Therefore, FRA is not required to provide an estimate of a public reporting burden in this document.

Federalism Implications

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

FRA analyzed this final rule under the principles and criteria in Executive Order 13132. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and the responsibilities among the various levels of government, as specified in the Executive Order 13132. In addition, FRA determined this rule does not impose substantial direct compliance costs on State and local governments. Accordingly, FRA concluded the consultation and funding requirements of Executive Order 13132 do not apply and preparation of a federalism assessment is not required.

Environmental Impact

FRA evaluated this final rule under its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined this final rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review under section 4(c)(20) of FRA's Procedures. *See* 64 FR 28547, May 26, 1999. Section 4(c)(20) reads as follows:

> (c) Actions categorically excluded. Certain classes of FRA actions have been determined to be categorically excluded from the requirements of these Procedures as they do not individually or cumulatively have a significant effect on the human environment. . . . The following classes of FRA actions are categorically excluded: . . . (20) Promulgation of railroad safety rules and policy statements that do not result in significantly increased emissions or air or water pollutants or noise or increased traffic congestion in any mode of transportation.

Consistent with section 4(c)(20) of FRA's Procedures, FRA concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. As a result, FRA finds this rule is not a major Federal action significantly affecting the quality of the human environment.

Unfunded Mandates Reform Act of 1995

Under Section 201 of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that

> before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement

detailing the effect on State, local, and tribal governments and the private sector. This final rule will not result in the expenditure of more than $156,000,000 by the public sector in any one year. Thus, preparation of such a statement is not required.

Energy Impact

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' 66 FR 28355, May 22, 2001. Under the Executive Order, a ''significant energy action'' is defined as any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of, a final rule or regulation (including a notice of inquiry, advance notice of proposed rulemaking, and notice of proposed rulemaking) that (1)(i) is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this rule under Executive Order 13211. FRA has determined this rule will not have a significant adverse effect on the supply, distribution, or use of energy, and, thus, is not a ''significant energy action'' under Executive Order 13211.

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) (91 FR 27534, May 10, 2012) require DOT agencies to achieve environmental justice 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 populations and low-income populations. The DOT Order instructs DOT agencies to address compliance with Executive Order 12898 and requirements within the DOT Order in rulemaking activities, as appropriate. FRA evaluated this final rule under Executive Order 12898 and the DOT Order and determined it would not cause disproportionately high and adverse human health and environmental effects on minority or low-income populations.

Executive Order 13175 (Tribal Consultation)

FRA evaluated this final rule under the principles and criteria in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, dated November 6, 2000. The final rule would not have a substantial direct effect on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal laws. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply, and a tribal summary impact statement is not required.

Trade Impact

The Trade Agreements Act of 1979 19 U.S.C. 2501 *et seq.*) prohibits Federal agencies from engaging in any standards setting or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. FRA assessed the potential effect of this final rule on foreign commerce and concluded its requirements are consistent with the Trade Agreements Act.

Privacy Act

Interested parties should be aware that anyone can search the electronic form of all written comments received into any agency docket by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** (65 FR 19477–19478, Apr. 11, 2000) or you may visit *http://www.transportation.gov/privacy.*

List of Subjects in 49 CFR Part 225

Investigations, Penalties, Railroad safety, Reporting and recordkeeping requirements.

The Rule

In consideration of the foregoing, FRA amends part 225 of chapter II, subtitle B of title 49, Code of Federal Regulations, as follows:

PART 225—[AMENDED]

■ 1. The authority citation for part 225 continues to read as follows:

Authority: 49 U.S.C. 103, 322(a), 20103, 20107, 20901–02, 21301, 21302, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 2. Amend § 225.27 by revising the first sentence of paragraph (c) to read as follows:

§ 225.27 Retention of records.

* * * * *

(c) Each railroad shall retain the original hard copy of each completed and signed Form FRA F 6180.55, ''Railroad Injury and Illness Summary,'' that the railroad submits to FRA on optical media (CD–ROM) or electronically via the Internet to *RsisAiReports@dot.gov* for at least five years after the calendar year to which it relates. * * *

* * * * *

■ 3. Amend § 225.37 by revising paragraph (c)(1) introductory text to read as follows:

§ 225.37 Optical media transfer and electronic submission.

* * * * *

(c)(1) Each railroad utilizing the electronic submission via the Internet option shall submit to FRA at *RsisAiReports@dot.gov:*

* * * * *

Issued in Washington, DC, on December 1, 2016.

Amitabha Bose,

Acting Administrator.

[FR Doc. 2016–29309 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160630573–6999–02]

RIN 0648–BG19

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Management Measures

Correction

In rule document 2016–28905 beginning on page 876971 in the issue of Friday, December 2, 2016, make the following correction:

1. On page 86971, in the first column, after the **DATES** heading, the second line, ''January 3, 2016.'' should read ''January 3, 2017.''

[FR Doc. C1–2016–28905 Filed 12–6–16; 8:45 am]

BILLING CODE 1301–00–D

Proposed Rules

Federal Register
Vol. 81, No. 235
Wednesday, December 7, 2016

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 ENERGY

10 CFR Part 205

RIN 1901–AB40

Grid Security Emergency Orders: Procedures for Issuance

AGENCY: Office of Electricity Delivery and Energy Reliability, U.S. Department of Energy.

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The U.S. Department of Energy is proposing to issue procedural regulations concerning the Secretary of Energy's issuance of an emergency order following the President's declaration of a Grid Security Emergency, under the Federal Power Act, as amended. The proposed procedures, if adopted, are intended to ensure the expeditious issuance of emergency orders under the Federal Power Act.

DATES: Public comment on this proposed rule will be accepted until February 6, 2017.

ADDRESSES: You may submit comments, identified by RIN 1901–AB40, by any of the following methods:

1. Follow the instructions for submitting comments on the Federal eRulemaking Portal at *http://www.regulations.gov.*
2. Send email to *oeregs@hq.doe.gov.* Include RIN 1901–AB40 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment.
3. Address postal mail to U.S. Department of Energy, Office of Electricity Delivery and Energy Reliability, Mailstop OE–20, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585.

Due to potential delays in the delivery of postal mail, we encourage respondents to submit comments electronically to ensure timely receipt.

This notice of proposed rulemaking, and any comments that DOE receives will be made available on regulations.gov. You may request a hardcopy of the comments be sent to you via postal mail by contacting *oeregs@hq.doe.gov* or the DOE's Office of Electricity Delivery and Energy Reliability at Mailstop OE–20, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Jeffrey Baumgartner, (202) 586–1411; U.S. Department of Energy, Office of Electricity Delivery and Energy Reliability, Mailstop OE–20, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585; or *oeregs@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

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I. Introduction and Background

On December 4, 2015, the President signed into law the Fixing America's Surface Transportation Act (''FAST Act'' or ''The Act''), Public Law 114–94. The Act contains several provisions designed to protect and enhance the Nation's electric power delivery infrastructure. Section 61003 of the Act adds a new section 215A, titled ''Critical Electric Infrastructure Security,'' to Part II of the Federal Power Act, codified at 16 U.S.C. 824o–1. New section 215A(a) defines, among other terms, a ''grid security emergency.'' New section 215A(b) authorizes the Secretary of Energy to order emergency measures after the President declares a grid security emergency. A grid security emergency could result from a physical attack, a cyber-attack using electronic communication or an electromagnetic pulse (EMP), or a geomagnetic storm event, damaging certain electricity infrastructure assets and impairing the reliability of the Nation's power grid. Emergency orders responding to grid security emergencies would aim to mitigate or eliminate threats to reliability as quickly and efficiently as possible. The statute authorizes the Secretary of Energy to issue orders for emergency measures as are necessary, in the Secretary's judgment, to protect or restore the reliability of critical electric infrastructure or defense critical electric infrastructure during the emergency. Critically, the Department's centralized direction following a declared grid security emergency will help the Department to coordinate resources efficiently to minimize the impact of the emergency.

The authority granted in section 215A of the Federal Power Act supplements the Secretary's existing authority, under section 202(c) of the Federal Power Act, to order temporary emergency measures if the Secretary finds ''that an emergency exists by reason of a sudden increase in the demand for electric energy, or a shortage of electric energy or of facilities for the generation or transmission of electric energy, or of fuel or water for generating facilities, or other causes,'' that the Secretary believes ''will best meet the emergency and serve the public interest.'' To that end, the Secretary may issue orders under section 202(c) requiring the ''temporary connections of facilities[,] generation, delivery, interchange, or transmission of electric energy.''

The FAST Act also directs the Secretary, ''after notice and opportunity for comment,'' to ''establish rules of procedure that ensure that such authority can be exercised expeditiously.'' To ensure that stakeholders and the public understand how the Department would issue an order responding to a grid security emergency, the Department proposes in this notice of proposed rulemaking the procedures it would expect to follow in the event of such emergency. DOE proposes to add these procedures to the existing subpart W in 10 CFR part 205.

Synopsis of the Notice of Proposed Rulemaking

A. General

Both natural and artificial events can disrupt the Nation's power grid. Geomagnetic storm events are

unavoidable natural phenomena, and an event of sufficient strength could compromise the grid. EMPs pose another significant threat. Cyber- and physical attacks on infrastructure could also damage or disrupt critical grid components. The Department is committed to minimizing any disruptions from an attack on, or natural damage to, the Nation's power grid. Responses to grid disruptions will need to be tailored to the particular circumstances, and the Department now has the authority to respond as necessary to mitigate the effects of a grid security emergency.

If the President should declare a grid security emergency, the Department intends to follow the procedures established in this rulemaking proceeding. The Secretary is authorized to issue emergency orders ''[w]henever the President issues and provides to the Secretary [of Energy] a written directive or determination identifying a grid security emergency.'' The purpose of an emergency order is to designate ''emergency measures as are necessary in the judgment of the Secretary to protect or restore the reliability of critical electric infrastructure or of defense critical electric infrastructure during such emergency.''

B. Definitions

The proposed rule begins with definitions of key terms in § 205.380. Further explanations for certain definitions and terms appear below.

''Bulk-power system'' encompasses the facilities used to transmit electricity and energy needed to maintain the reliability of that system of interconnected facilities—in essence, the electric power grid for which the President might declare a grid security emergency and authorize the Secretary to issue emergency orders to protect or restore its reliability. The term excludes facilities used in local electric distribution. This definition is drawn from the statutory definition applicable throughout section 215A of the Federal Power Act.

''Commission'' refers to the Federal Energy Regulatory Commission, which is responsible for approving applicable reliability standards. This term does not apply here to State regulatory commissions or to the former Federal Power Commission.

''Electric Reliability Organization'' refers to the organization, certified by the Commission under section 215(c) of the Federal Power Act, which establishes and enforces reliability standards with Commission oversight. As of this rulemaking, the Commission's designated Electric Reliability Organization is the North American Electric Reliability Corporation (NERC).

''Electricity Information Sharing and Analysis Center'' (E–ISAC) refers to the organization, operated on behalf of the electricity subsector by the North American Electric Reliability Corporation, that gathers and analyzes security information, coordinates incident management, and communicates mitigation strategies with stakeholders within the electricity subsector, across interdependent sectors, and with government partners. E–ISAC is one of the organizations with which the Secretary will consult, to the extent practicable, in issuing an emergency order.

The ''Electricity Subsector Coordinating Council'' (ESCC) refers to the organization that aims to foster and facilitate the coordination of sector-wide, policy-related activities and initiatives designed to improve the reliability and resilience of the electricity subsector, including physical and cyber security infrastructure. The ESCC is another of the organizations with which the Secretary will consult, to the extent practicable, in issuing an emergency order. DOE considers the ''electricity subsector'' to include commercial and industrial actors who generate and deliver electric power, along with the facilities those actors use to generate and deliver the power.

An ''Electromagnetic pulse'' is one (1) or more pulses of electromagnetic energy emitted by a device capable of disabling or disrupting operation of, or destroying, electronic devices or communications networks, including hardware, software, and data, by means of such a pulse. The pulse can be accidental, incidental, or malicious.

The ''Emergency & Incident Management Council'' (EIMC) is the organization, internal to the Department and chaired by the Deputy Secretary of Energy, designed to increase cooperation and coordination across the Department to prepare for, mitigate, respond to, and recover from emergencies. The EIMC plays a central role in Grid Security Emergency orders, as it will meet, if practicable, after the President declares the emergency to prepare recommendations to the Secretary.

''Geomagnetic storm'' refers to a temporary disturbance of the Earth's magnetic field resulting from solar activity. These natural phenomena are sometimes powerful enough to disrupt the Bulk-power system. If the disruption is sufficiently severe, a Grid Security Emergency could result.

''Regional entity'' refers to organizations responsible for enforcing reliability standards for the Bulk-power system in certain, defined regions. These organizations operate under NERC and Commission oversight.

C. Summary of Proposed Rule

As described in proposed § 205.381, orders issued under section 215A(b) of the Federal Power Act may apply to the pertinent Electric Reliability Organization (NERC, as of this rulemaking), regional entity, or ''any owner, user, or operator of critical electric infrastructure or of defense critical electric infrastructure within the United States.''

The procedures are designed to allow the Secretary to address a declared grid security emergency. The statute authorizes the Secretary to order response measures that the Secretary believes are necessary to protect or restore the reliability of certain infrastructure in a grid security emergency. Because the nature of a grid security emergency is uncertain, the procedures allow for flexibility in response measures and, as the statute requires, to ''ensure that such authority can be exercised expeditiously.'' While the procedures are expected to produce the most efficient and effective emergency response possible under the circumstances, the Secretary has final authority to issue appropriate grid security emergency orders.

In the event of a grid security emergency, DOE will immediately activate its unified command structure and coordinate outreach efforts. DOE expects that the EIMC will anchor the Department's proposed response via its recommendations to the Secretary. Based on the nature and timing of the emergency, however, the Secretary would maintain discretion, based on a judgment of the relevant circumstances, to issue an emergency order without EIMC input. To the extent practicable, DOE will promptly alert stakeholders of the grid security emergency through existing alert mechanisms, such as the NERC alert system and ESCC communication coordination processes.

Proposed § 205.382 outlines the EIMC procedures. When the Department is notified, in writing, that the President has declared a grid security emergency and has directed the Secretary to order emergency response measures, the EIMC will be activated. The EIMC will create ad hoc task groups, assign recommendation development tasks to these groups, and coordinate the Department's consultation efforts. The EIMC may take other actions but only as necessary and practicable to develop the Department's recommendations to the Secretary. After the EIMC makes its

recommendations, the Secretary will issue the emergency order. Again, the Department would follow these procedures to the extent practicable, but subject to the Secretary's judgment of the urgency of the situation and the best approach under the circumstances.

Consistent with the Department's longstanding practice, all reasonable efforts will be made to consult with stakeholders prior to the issuance of an emergency order. The statute also requires the Secretary to consult with other governmental authorities and non-governmental entities before issuing emergency orders, ''to the extent practicable in light of the nature of the grid security emergency and the urgency of the need for action.'' The Department understands that electric reliability entities and private industry will likely be impacted by the emergency and have important situational awareness to assist the Department in identifying mitigation or protection measures. Proposed § 205.383 outlines how the Department will coordinate its communication with other entities. Within the Department, the Office of Electricity Delivery and Energy Reliability (OE) will be the lead program office supporting the Secretary in issuing grid security emergency orders. As set forth in this proposed rule, OE would be responsible for conducting the required consultations under the statute. Consultation would include the Department's effort to obtain information and recommended emergency measures from those government entities,[1] electric reliability entities, and owners, users, or operators of critical electric infrastructure or of defense critical electric infrastructure—including private-sector entities—impacted by the emergency. Historically, the Department has collaborated with other Federal agencies in an energy emergency to obtain waivers or special permits to facilitate expedited restoration. Here, the Department also intends to work with other Federal agencies to obtain waivers or special permits necessary to comply with the Secretary's order.

After the Secretary issues an emergency order, the Department will communicate the order's content to the entities subject to the order, as noted in proposed § 205.384. The Department will also enlist the ESCC and E–ISAC to communicate the order's content to those affected. The Department will also use any other form of communication most appropriate under the circumstances. Optimal communication on grid security emergencies will be paramount during the emergency, and the Department will work to ensure that information is shared that will help it to respond most effectively. For that reason, according to proposed § 205.384 and consistent with obligations to protect classified information, the Secretary may declassify information eligible for that change in status to ensure maximum distribution of information critical to the emergency response.

This proposed rule is limited to the Department's procedures for issuing an emergency order in response to a grid security emergency. Should the Secretary issue such an order, the order itself would set out the requirements and procedures for impacted entities to seek clarification or reconsideration of that particular order. Proposed § 205.385 provides general requirements for such requests. In particular, DOE proposes that anyone subject to a particular order may submit a request for clarification or reconsideration in writing to the Secretary. The requests would be posted on the Department's Web site consistent with criteria established for treatment of critical electric infrastructure information. In acting on a request for clarification or reconsideration, the Secretary may grant or deny the request or may abrogate or modify the final order, in whole or in part, with or without further proceedings, as soon as practicable. Such a request would not stay an emergency order unless the Secretary so determined.

As warranted, and to the extent practicable and consistent with obligations to protect classified information, the Secretary may allow key personnel of ordered entities temporary access to classified information. Proposed § 205.386 sets out this approach.

Proposed § 205.387 describes termination of grid security emergency orders. An emergency order remains effective for up to fifteen (15) days and may be extended for subsequent periods of up to 15 days if the President issues another directive to the Secretary that the original emergency has not ended or that the emergency measures already ordered are still required. If warranted, the Secretary may also terminate an order before the 15 days have elapsed. The entity or entities subject to the emergency order may also request that the Secretary terminate an order if the entity or entities believes that the grid security emergency ceases to exist and that protection or restoration of the grid has been achieved.

The Department also plans to determine compliance with grid security emergency orders, as described in proposed § 205.388. At the time the Department issues an emergency order, or shortly after the issuance, the Department may require the ordered party to provide a detailed account of compliance actions. As noted in proposed § 205.389, enforcement provisions in Part III of the Federal Power Act also apply to orders issued under section 215A. *See* 42 U.S.C. 7151(b) & 7172(a)(2)(A). For appeal purposes, as noted in proposed § 205.390, the Federal Power Act includes the requirements for a rehearing request and the process for an appeal of a decision.

As indicated in proposed § 205.391, the Department will not adjudicate cost recovery under an emergency order, as that determination is reserved for the Commission, state regulators, or the United States Court of Federal Claims. Specifically, the FAST Act allows the Commission to ''establish a mechanism'' allowing an aggrieved party to recover costs, but only if it determines that such a party has ''incurred substantial costs to comply with an order for emergency measures issued under [section 215A] and that such costs were prudently incurred and cannot reasonably be recovered through regulated rates or market prices for the electric energy or services sold by'' the aggrieved party.

Finally, the FAST Act shields parties affected by emergency orders from liability for what would otherwise be violations of the Federal Power Act or the reliability standards, except in cases of gross negligence. New section 215A(f) of the Federal Power Act states that any action or omission taken to comply with an emergency order that causes noncompliance ''with any rule, order, regulation, or provision'' of the Federal Power Act, as well as any FERC-approved reliability standard, ''shall not be considered a violation'' of that legal requirement. The same subsection incorporates the liability protection for emergency orders issued under section 202(c) of the Federal Power Act. That protection, for actions or omissions resulting in noncompliance with ''any Federal, State, or local environmental law or regulation,'' not only frees the ordered party from violations of those laws or regulations, but also shields the

[1] DOE notes that the regulatory text of proposed § 205.383 discusses consultation with agencies supporting Emergency Support Function (ESF) #12. For clarification, ESF #12 is the Department of Energy's responsibility to help reestablish damaged energy systems and components when an incident requires a coordinated Federal response. The scope of ESF #12 includes providing technical expertise; collecting, evaluating, and sharing information on energy system damage; estimating the impact of system outages locally, regionally, and nationally; helping government and private sector entities overcome challenges in reestablishing energy system; and providing information about the status of energy reestablishment efforts.

ordered party from ''any requirement, civil or criminal liability, or a citizen suit under such environmental law or regulation,'' even if a court subsequently stays, modifies, or sets aside the order. Proposed § 205.392 describes all of these protections.

III. Public Participation

A. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this proposed rule.

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

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

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

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

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

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

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

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

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

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

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

IV. Regulatory Review

A. Executive Order No. 12,866

This proposed rule has been determined to be a significant regulatory action under Executive Order No. 12,866, ''Regulatory Planning and Review,'' 58 FR 51,735 (Oct. 4, 1993). Accordingly, this action was subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

B. National Environmental Policy Act

DOE has determined that this proposed rule is covered under the Categorical Exclusion found in the DOE's National Environmental Policy Act regulations at paragraph A6 Rulemakings, procedural of appendix A to subpart D, 10 CFR part 1021, which applies to Rulemakings that are strictly procedural, such as rulemaking (under 48 CFR part 9) establishing procedures for technical and pricing proposals and establishing contract clauses and contracting practices for the purchase of goods and services, and rulemaking (under 10 CFR part 600) establishing application and review procedures for, and administration, audit, and closeout of, grants and cooperative agreements. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation

of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order No. 13,272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53,461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE's procedures and policies are available on the Office of General Counsel's Web site: *http://www.energy.gov/gc/downloads/executive-order-13272-consideration-small-entities-agency-rulemaking.*

DOE has reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. This proposed rule sets forth procedures that DOE expects to use to issue an order in the event of a declared grid security emergency. The procedures govern DOE activities in the issuance of an order and therefore impact DOE, a Federal agency, rather than any small entities.

DOE further expects that these orders would be issued rarely. In addition, the FAST Act authorizes DOE to issue orders only to specific entities—namely, the pertinent Electric Reliability Organization (NERC, as of this rulemaking), regional entity, or any owner, user or operator of critical energy infrastructure or defense critical energy infrastructure. DOE has determined that these entities most likely fall under NAICS code 221121, ''Electric Bulk Power Transmission and Control.'' To be considered a small entity, these businesses must have 500 employees or less. Due to the nature of the orders to protect or restore and/or infrastructure, DOE has determined that it is likely to consult with large businesses.

An entity subject to an order may request the clarification or rehearing of an order, or the termination of an order. DOE does not expect that these provisions, which would help an entity to understand an order or, in the case of a termination granted by the Secretary, end the applicability of an order, to impose a significant impact on any entity. DOE may also consult with any of these entities to understand the grid security emergency and obtain recommendations to address the emergency. DOE also does not expect these consultations to result in a significant impact on any entity because the interaction would not order the entity to perform any action, but would rather be an exchange of information to help DOE understand the emergency and consider measures to protect and/or restore infrastructure. In addition, it is likely that only entities with equities that could be impacted by potential orders would be consulted. In the event that an order is issued to address a grid security emergency, because the contents of any order would be highly dependent upon the nature of the grid security emergency, DOE again emphasizes that the order itself, rather than these procedures, would specify the requirements necessary to address the grid security emergency.

On the basis of the foregoing, DOE certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

D. Paperwork Reduction Act

This proposed rule does not contain information collection requirements subject to approval by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act at 5 CFR part 1320. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

E. Unfunded Mandates Reform Act of 1995

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

This proposed rule will establish the procedures DOE expects to use issue an order in the event of a declared grid security emergency. In the event that an order is issued to address a grid security emergency, the order itself, rather than these procedures, would specify the requirements necessary to address the grid security emergency. The proposed rule will not result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year. Accordingly, no assessment or analysis is required under the Unfunded Mandates Reform Act of 1995.

F. Treasury and General Government Appropriations Act, 1999

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

G. Executive Order No. 13,132

Executive Order No. 13,132, ''Federalism,'' 64 FR 43,255 (Aug. 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it will not preempt State law and will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This proposed

rule would establish the procedures DOE expects to use issue an order in the event of a declared grid security emergency. In the event that an order is issued to address a grid security emergency, the order itself, rather than these procedures, would specify the requirements necessary to address the grid security emergency. No further action is required by Executive Order No. 13,132.

H. Executive Order No. 12,988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order No. 12,988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order No. 12,988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order No. 12,988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or whether it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order No. 12,988.

I. Treasury and General Government Appropriations Act, 2001

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

OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62,446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Executive Order No. 13,211

Executive Order No. 13,211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28,355 (May 22, 2001) requires Federal agencies to prepare and submit to the OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order No. 12,866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action will not have a significant adverse effect on the supply, distribution, or use of energy. The proposed rule would establish the procedures DOE expects to use issue an order in the event of a declared grid security emergency. In the event that an order is issued to address a grid security emergency, the order itself, rather than these procedures, would specify the requirements necessary to address the grid security emergency. In addition, the statute requires that the order must ''protect or restore'' critical electric infrastructure or defense critical electric infrastructure. Therefore, the rule is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects in 10 CFR Part 205

Administrative practice and procedure, Energy, and Recordkeeping and reporting requirements.

Issued in Washington, DC, on November 23, 2016.

Patricia Hoffman,

Assistant Secretary, Office of Electricity Delivery and Energy Reliability.

For the reasons stated in the preamble, DOE proposes to amend part 205 of chapter II, subchapter A, of Title 10 of the Code of Federal Regulations, as set forth below:

PART 205—ADMINISTRATIVE PROCEDURES AND SANCTIONS

■ 1. The authority citation for part 205 continues to read as follows:

Authority: Department of Energy Organization Act, Pub. L. 95–91, 91 Stat. 565 (42 U.S.C. Section 7101). Federal Power Act, Pub. L. 66–280, 41 Stat. 1063 (16 U.S.C. Section 792) *et seq.,* Department of Energy Delegation Order No. 0204–4 (42 FR 60726). E.O. 10485, 18 FR 5397, 3 CFR, 1949–1953, Comp., p. 970 as amended by E.O. 12038, 43 FR 4957, 3 CFR 1978 Comp., p. 136.

■ 2. Part 205 is amended by revising the heading of subpart W to read as follows:

Subpart W—Electric Power System Permits and Reports; Applications; Administrative Procedures and Sanctions; Grid Security Emergency Orders

■ 3. Subpart W is amended by adding an undesignated center heading after § 205.379 to read as follows:

* * * * *

Internal Procedures for Issuance of a Grid Security Emergency Order

■ 4. Sections 205.380 through 250.392 are added to subpart W to read as follows:

Sec.
§ 205.380 Definitions.
§ 205.381 Application of emergency order.
§ 205.382 Procedures for issuing an emergency order.
§ 205.383 Outreach and consultation.
§ 205.384 Communication of orders.
§ 205.385 Clarification or reconsideration.
§ 205.386 Temporary access to classified information.
§ 205.387 Termination of an emergency order.
§ 205.388 Tracking compliance.
§ 205.389 Enforcement.
§ 205.391 Cost recovery.
§ 205.392 Liability exemptions.

§ 205.380 Definitions.

As used in this part:

Bulk-power system means:

(1) Facilities and control systems necessary for operating an interconnected electric energy transmission network (or any portion thereof); and

(2) Electric energy from generation facilities needed to maintain transmission system reliability.

(3) The term does not include facilities used in the local distribution of electric energy.

Commission means the Federal Energy Regulatory Commission.

Critical electric infrastructure means a system or asset of the bulk-power system, whether physical or virtual, the incapacity or destruction of which would negatively affect national security, economic security, public health or safety, or any combination of such matters.

Defense critical electric infrastructure means any electric infrastructure located in any of the 48 contiguous States or the District of Columbia that serves a facility designated by the Secretary as:

(1) Critical to the defense of the United States; and

(2) Vulnerable to a disruption of the supply of electric energy provided to such facility by an external provider, but that is not owned or operated by the owner or operator of such facility.

Department means the United States Department of Energy.

Electric reliability organization means the organization, certified by the Commission under section 215(c) of the Federal Power Act, 16 U.S.C. 824o(c), the purpose of which is to establish and enforce reliability standards for the bulk-power system, subject to Commission review.

Electricity information sharing and analysis center means the organization, operated on behalf of the electricity subsector by the Electric Reliability Organization, that gathers and analyzes security information, coordinates incident management, and communicates mitigation strategies with stakeholders within the electricity subsector, across interdependent sectors, and with government partners. The E–ISAC, in collaboration with the Department of Energy and the Electricity Subsector Coordinating Council (ESCC), serves as the primary security communications channel for the electricity subsector and enhances the subsector's ability to prepare for and respond to cyber and physical threats, vulnerabilities, and incidents.

Electricity subsector coordinating council means the organization that aims to foster and facilitate the coordination of sector-wide, policy-related activities and initiatives designed to improve the reliability and resilience of the electricity subsector, including physical and cyber security infrastructure.

Electromagnetic pulse means one or more pulses of electromagnetic energy emitted by a device capable of disabling or disrupting operation of, or destroying, electronic devices or communications networks, including hardware, software, and data, by means of such a pulse.

Emergency & incident management council means the organization, internal to the Department of Energy and chaired by the Deputy Secretary of Energy, designed to increase cooperation and coordination across the Department to prepare for, mitigate, respond to, and recover from emergencies.

Geomagnetic storm means a temporary disturbance of the Earth's magnetic field resulting from solar activity.

Grid security emergency means the occurrence or imminent danger of:

(1) A malicious act using electronic communication or an electromagnetic pulse, or a geomagnetic storm event, that could disrupt the operation of those electronic devices or communications networks, including hardware, software, and data, that are essential to the reliability of critical electric infrastructure or of defense critical electric infrastructure; and

(2) Disruption of the operation of such devices or networks, with significant adverse effects on the reliability of critical electric infrastructure or of defense critical electric infrastructure, as a result of such act or event; or

(3) A direct physical attack on critical electric infrastructure or on defense critical electric infrastructure; and

(4) Significant adverse effects on the reliability of critical electric infrastructure or of defense critical electric infrastructure as a result of such physical attack.

Regional entity means an entity having enforcement authority under section 215(e)(4) of the Federal Power Act, 16 U.S.C. 824o(e)(4).

Secretary means the Secretary of Energy.

§ 205.381 Application of emergency order.

An order for emergency measures under section 215A(b) of the Federal Power Act may apply to the Electric Reliability Organization, a regional entity, or any owner, user, or operator of critical electric infrastructure or of defense critical electric infrastructure within the United States.

§ 205.382 Procedures for issuing an emergency order.

(a) The Secretary has final authority and may act as quickly as necessary to address the emergency. The Secretary will adhere to these procedures unless, in the Secretary's judgment, the emergency requires alternative procedures.

(b) Upon the Department's receipt of the President's written directive or determination identifying a Grid Security Emergency, the Emergency & Incident Management Council (Council) will convene at least one emergency meeting. Resulting from this meeting, the Council's responsibilities will include, but not be limited to:

(1) Assigning consultation and situational awareness tasks;

(2) Creating ad hoc task groups; and

(3) Assigning recommendation development tasks to the ad hoc task groups it has created.

(c) The Council will present its recommendations to the Secretary as expeditiously as possible and practicable. As quickly as the situation requires, following presentation of the Council's recommendations, the Secretary will issue the emergency order.

§ 205.383 Outreach and consultation.

The Department of Energy's Office of Electricity Delivery and Energy Reliability will conduct consultation related to any order issued by the Secretary in response to a declared Grid Security Emergency. Before the issuance of any order, to the extent practicable in light of the nature of the Grid Security Emergency and the urgency of the need for action, outreach efforts will be made to consult at least the following: Authorities in the government of Canada; authorities in the government of Mexico; appropriate Federal agencies including, but not limited to, those supporting Emergency Support Function No. 12; the Commission; and at least the following non-government entities: The Electricity Subsector Coordinating Council, the Electric Reliability Organization, regional entities, and owners, users, or operators of Critical Electric Infrastructure or of Defense Critical Electric Infrastructure within the United States. Consultation will include the Department's effort to obtain information related to the Grid Security Emergency and recommended emergency measures from those governments, electric reliability entities, and private sector companies impacted by the emergency.

§ 205.384 Communication of orders.

The Department will communicate the content of emergency orders issued by the Secretary to the parties subject to the order. The Department will also rely on existing coordinating bodies, such as the Electricity Subsector Coordinating Council and the Electricity Information Sharing and Analysis Center, in addition to any other form or forms of communication most expedient under the circumstances, to communicate the content of emergency orders issued by

the Secretary. To the extent practicable under the circumstances, efforts will be made to declassify information to ensure maximum distribution.

§ 205.385 Clarification or reconsideration.

Any request for clarification or reconsideration of an emergency order issued under section 215A(b) of the Federal Power Act must be submitted in writing to the Secretary, and will be posted on the DOE Web site consistent with CEII criteria. The Secretary may, in his sole discretion, order a stay of the emergency order for which such clarification or rehearing is sought. The Secretary may grant or deny the request for clarification or reconsideration, or may abrogate or modify the order, in whole or in part, with or without further proceedings, as soon as practicable.

§ 205.386 Temporary access to classified information.

To the extent practicable, and consistent with obligations to protect classified information, the Secretary may provide temporary access to classified information, related to a Grid Security Emergency for which emergency measures are issued, to key personnel of any entity subject to such emergency measures. The purpose of this access is to enable optimum communication between the entity and the Secretary and other appropriate Federal agencies regarding the Grid Security Emergency.

§ 205.387 Termination of an emergency order.

(a) An order for emergency measures shall expire no later than 15 days after its issuance. The Secretary may reissue an order for emergency measures for subsequent periods, not to exceed 15 days for each such period, provided that the President, for each such period, issues and provides to the Secretary a written directive or determination that the Grid Security Emergency for which the Secretary intends to reissue an emergency order continues to exist or that the emergency measures continue to be required.

(b) The Secretary may rescind an emergency order after finding that the Grid Security Emergency for which that order was issued has ended and that protective or mitigation measures required by the order have been sufficiently taken.

(c) An entity or entities subject to an emergency order under this rule may, at any time, request termination of the emergency order by demonstrating, in a petition to the Secretary, that the emergency no longer exists and that protective or mitigation measures required by the order have been sufficiently taken.

§ 205.388 Tracking compliance.

Beginning at the time the Secretary issues an emergency order, the Department may require the ordered party to provide a detailed account of actions taken to comply with the terms of the order.

§ 205.389 Enforcement.

In accordance with Part III of the Federal Power Act, the Secretary may take or seek enforcement action against ordered parties who fail to comply with the terms of an order issued under section 215A(b) of that Act.

§ 205.390 Rehearing and Judicial Review.

The procedures of Part III of the Federal Power Act apply to motions for rehearing of orders issued under section 215A(b) of that Act filed for the purpose of preserving appellate rights.

§ 205.391 Cost recovery.

A party seeking recovery of costs associated with compliance with an order issued under section 215A(b) of the Federal Power Act must petition the appropriate State regulatory agency, the United States Court of Federal Claims, or the Commission for relief.

§ 205.392 Liability exemptions.

To the extent any action or omission taken by an entity that is necessary to comply with an order for emergency measures issued by authority of section 215A(b) of the Federal Power Act and pursuant to this Part, including any action or omission taken to voluntarily comply with such order, results in noncompliance with, or causes such entity not to comply with any rule, order, regulation, or provision of or under that Act, including any reliability standard approved by the Commission pursuant to section 215 of that Act, such action or omission shall not be considered a violation of such rule, order, regulation, or provision. Further, an action or omission by an owner, operator, or user of Critical Electric Infrastructure or of Defense Critical Electric Infrastructure to comply with an order for emergency measures issued under section 215A(b) of the Federal Power Act shall be treated as an action or omission taken to comply with an order issued under section 202(c) of that Act for purposes of such section. These liability exemptions shall not apply to an entity that, in the course of complying with an order for emergency measures issued under section 215A(b) of the Federal Power Act by taking an action or omission for which the entity would otherwise be liable, takes such action or omission in a grossly negligent manner.

[FR Doc. 2016–28974 Filed 12–6–16; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6436; Directorate Identifier 2015–SW–037–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Airbus Helicopters Deutschland GmbH (Airbus Helicopters) Model MBB–BK117 C–2 helicopters. This proposed AD would require inspecting the pilot collective wiring harness. This proposed AD is prompted by a report that a heat-shrinkable sleeve prevented the twist grip on the collective from being fully engaged during a flight test. The proposed actions are intended to prevent failure of the hoist or emergency landing gear flotation systems due to chafing of wiring caused by an incorrectly installed heat-shrinkable sleeve.

DATES: We must receive comments on this proposed AD by February 6, 2017.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6436; or in person at the Docket

Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.com/techpub.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: George Schwab, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *george.schwab@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2015–0144, dated July 21, 2015, to correct an unsafe condition for Airbus Helicopters Model MBB–BK117 C–2 helicopters, up to serial number 9708. EASA advises that, during a flight test, the pilot could not fully engage a twist grip on a Model MBB–BK117 C–2 helicopter. According to EASA, further investigation found a transparent sleeve on the collective lever wiring harness damaged because of incorrect installation of the heat-shrinkable sleeve. This condition, if not detected and corrected, could result in chafing of the harness, leading to the malfunction of the affected systems, EASA advises. EASA consequently requires a one-time inspection of the heat-shrinkable and transparent sleeves installed on the collective lever wiring harness.

FAA's Determination

These helicopters have been approved by the aviation authority of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with Germany, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

We reviewed Airbus Helicopters Alert Service Bulletin ASB MBB–BK117 C–2–88A–010, Revision 1, dated April 16, 2015 (ASB), which specifies a visual inspection of the heat-shrinkable sleeve for correct position. If the sleeve's position is incorrect, the ASB specifies shortening the sleeve. If there is any damage, the ASB calls for replacing the damaged parts.

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

Proposed AD Requirements

This proposed AD would require, within 100 hours time-in-service, visually inspecting the pilot collective wiring harness for correct position of the heat-shrinkable sleeve and the transparent sleeve. If the heat-shrinkable and the transparent sleeves are in their correct positions, this proposed AD would require re-installing the collective lever. If the heat-shrinkable sleeve is closer to or below the torque tube tangs, this proposed AD would require shortening the heat-shrinkable sleeve. If the transparent sleeve is damaged, this proposed AD would require replacing the heat-shrinkable sleeve, transparent sleeve, and identification sleeve. Lastly, this proposed AD would require replacing any damaged wires in the wiring harness.

Differences Between This Proposed AD and the TCCA AD

The compliance time in the EASA AD is based on whether the helicopter has an externally mounted hoist or emergency flotation system. This proposed AD would require compliance within 100 hours time-in-service for all applicable helicopters.

Costs of Compliance

We estimate that this proposed AD would affect 113 helicopters of U.S. Registry and that labor costs average $85 a work hour.

- Inspecting the pilot collective wiring harness for the correct position of the heat-shrinkable sleeve would require 1.5 work hours. No parts would be required for a total cost of $128 per helicopter and $14,464 for the U.S. fleet.
- Replacing or repairing the sleeves would require 5.5 work hours and parts would cost $10, for a total cost of $478 per helicopter.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and

responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus Helicopters Deutschland GmbH Helicopters: Docket No. FAA–2016–6436; Directorate Identifier 2015–SW–037–AD.

(a) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model MBB–BK 117 C–2 helicopters, serial numbers 9004 through 9708, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as an incorrectly installed heat-shrinkable sleeve on the collective lever wiring harness. This condition could result in chafing of the wiring and subsequent failure of the hoist cable cutter or emergency landing gear flotation systems.

(c) Comments Due Date

We must receive comments by February 6, 2017.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 100 hours time-in-service, remove the pilot collective lever and visually inspect the pilot collective lever wiring harness for proper installation of the heat-shrinkable sleeve and transparent sleeve and for damage in accordance with paragraph 3.B.2.1 and as depicted in Figure 2 of Airbus Helicopters Alert Service Bulletin MBB–BK117 C–2–88A–010, Revision 1, dated April 16, 2015 (ASB).

(1) If the heat-shrinkable sleeve and transparent sleeve are installed as depicted in Figure 2 of the ASB and there is no damage, install the collective lever in accordance with paragraphs 3.B.2.3.a through 3.B.2.3.f of the ASB.

(2) If the heat-shrinkable sleeve or transparent sleeve is installed as depicted in Figure 3, Detail B of the ASB, alter the heat-shrinkable sleeve as depicted in Figure 3, Detail C.

(3) If the transparent sleeve is damaged as depicted in Figure 4, Detail D of the ASB, replace the heat-shrinkable sleeve, transparent sleeve, and identification sleeve. Replace any wire that has a nick, scratch, cut, or is frayed.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: George Schwab, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2015–0144, dated July 21, 2015. You may view the EASA AD on the Internet at *http://www.regulations.gov* in the AD Docket.

(h) Subject

Joint Aircraft Service Component (JASC) Code: Wheel/Ski/Float/Emergency Equipment, 3246/2560.

Issued in Fort Worth, Texas, on November 21, 2016.

Lance T. Gant,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–28670 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9167; Directorate Identifier 2016–NE–20–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain General Electric Company (GE) GE90 turbofan engines. This proposed AD was prompted by a report of an engine and airplane fire. This proposed AD would require replacing affected fuel/oil lube/servo coolers (''main heat exchangers'') with a part eligible for installation. We are proposing this AD to prevent failure of a main heat exchanger, which could result in an engine fire.

DATES: We must receive comments on this proposed AD by January 23, 2017.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact General Electric Company, GE-Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215, phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.* You may view this referenced service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9167; or in person at the Docket Management Facility between 9 a.m.

and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: John Frost, Aerospace Engineer, Engine Certification Office, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7756; fax: 781–238–7199; email: *john.frost@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–FAA–2016–9167; Directorate Identifier 2016–NE–20–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We propose to adopt an AD for certain GE GE90–76B, GE90–85B, GE90–90B, GE90–94B, GE90–110B1, and GE90–115B turbofan engines with a main heat exchanger, part number (P/N) 1838M88P11 or 1838M88P13.

This proposed AD is prompted by a report of an airplane fire caused by a failed main heat exchanger. The incident investigation determined the cause to be an internal main heat exchanger tube separation, which resulted in leakage of fuel into the oil system, causing oil sump flooding that overwhelmed the scavenge and venting system. This condition, if not corrected, could result in failure of a main heat exchanger, which could cause an engine fire. To correct this unsafe condition, we propose to require replacing the main heat exchanger with a part not affected by this proposed AD or with a part that is repaired in accordance with the manufacturer's service information.

Related Service Information Under 1 CFR Part 51

We reviewed GE Service Bulletin (SB) GE90–100 SB 79–0034, Revision 03, dated August 5, 2016, and SB GE90 SB 79–0058, Revision 02, dated August 5, 2016. This service information describes procedures to replace and repair a main heat exchanger. These documents are distinct since they apply to different engine models.

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

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require replacing the affected main heat exchangers with a part eligible for installation.

Costs of Compliance

We estimate that this proposed AD affects 185 engines installed on airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace main heat exchanger	5 work-hours × $85 per hour = $425	$7,000	$7,425	$1,373,625

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

General Electric Company: Docket No. FAA–2016–9167; Directorate Identifier 2016–NE–20–AD.

(a) Comments Due Date

We must receive comments by January 23, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) GE90–76B, GE90–85B, GE90–90B, GE90–94B, GE90–110B1, and GE90–115B turbofan engines with a fuel/oil lube/servo cooler (''main heat exchanger'') part number (P/N) 1838M88P11 or 1838M88P13, with a serial number listed in paragraph 1.A of GE Service Bulletin (SB) GE90–100 SB 79–0034, Revision 03, dated August 05, 2016; or SB GE90 SB 79–0058, Revision 02, dated August 05, 2016.

(d) Subject

Joint Aircraft System Component (JASC) Code 7921, Engine Oil Cooler.

(e) Unsafe Condition

This AD was prompted by an engine and airplane fire. We are issuing this AD to prevent failure of a main heat exchanger, which could result in an engine fire.

(f) Compliance

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

(g) Required Actions

Within 12 months after the effective date of this AD, replace the main heat exchanger with a part eligible for installation.

(h) Definition

For purposes of this AD, a part eligible for installation is a main heat exchanger with a P/N and serial number not listed in paragraph (c) of this AD or a main heat exchanger repaired in accordance with the Accomplishment Instructions, paragraphs 3.C.(2) through 3.C.(7), of GE SB GE90–100 SB 79–0034, dated December 3, 2014; Revision 01, dated August 14, 2015; Revision 02, dated November 6, 2015; or Revision 03, dated August 5, 2016; or GE SB GE90 SB 79–0058, dated August 18, 2015; Revision 01, dated December 10, 2015; or Revision 02, dated August 05, 2016.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact John Frost, Aerospace Engineer, Engine Certification Office, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7756; fax: 781–238–7199; email: *john.frost@faa.gov.*

(2) For service information identified in this AD, contact General Electric Company, GE-Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215, phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.*

(3) You may view this referenced service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on November 16, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–28667 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA—2016–0014]

RIN 1218–AD 08

Prevention of Workplace Violence in Healthcare and Social Assistance

AGENCY: Occupational Safety and Health Administration (OSHA), DOL.

ACTION: Request for Information (RFI).

SUMMARY: Workplace violence against employees providing healthcare and social assistance services is a serious concern. Evidence indicates that the rate of workplace violence in the industry is substantially higher than private industry as a whole. OSHA is considering whether a standard is needed to protect healthcare and social assistance employees from workplace violence and is interested in obtaining information about the extent and nature of workplace violence in the industry and the nature and effectiveness of interventions and controls used to prevent such violence. This RFI provides an overview of the problem of workplace violence in the healthcare and social assistance sector and the measures that have been taken to address it. It also seeks information on issues that might be considered in developing a standard, including scope and the types of controls that might be required.

DATES: Submit comments on or before April 6, 2017. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments and additional materials by any of the following methods:

Electronically: Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

Facsimile: OSHA allows facsimile transmission of comments and additional material that are 10 pages or fewer in length (including attachments). Send these documents to the OSHA Docket Office at (202) 693–1648. OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (for example, studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Technical Data Center, Room N–3653, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. These attachments must identify clearly the sender's name, the date, subject, and docket number OSHA–2016–0014 so that the Docket Office can attach them to the appropriate document.

Regular mail, express mail, hand delivery, or messenger (courier) service: Submit comments and any additional material (for example, studies, journal articles) to the OSHA Docket Office, Docket No. OSHA–2016–0014 or RIN 1218–AD 08, Technical Data Center, Room N–3653, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, and messenger service. The hours of operation for the OSHA Docket Office are 10 a.m. to 3:00 p.m., e.t.

Instructions: All submissions must include the Agency's name and the docket number for this Request for Information (OSHA–2016–0014). OSHA will place comments and other material, including any personal information, in the public docket without revision, and these materials will be available online at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting statements they do not want made available to the public and submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

If you submit scientific or technical studies or other results of scientific research, OSHA requests (but is not

requiring) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (*e.g.,* consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking and policy options discussed in this RFI. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the record will be considered by the Agency if it engages in rulemaking.

Docket: To read or download submissions or other material in the docket, go to: *http://www.regulations.gov* or the OSHA Docket Office at the address above. The *http://www.regulations.gov* index lists all documents in the docket. However, some information (*e.g.,* copyrighted material) is not available publicly to read or download through the Web site. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press Inquiries: Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: 202–693–1999; email: *Meilinger.Francis2@dol.gov.*

General and technical information: Lyn Penniman, OSHA Directorate of Standards and Guidance, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: 202–693–2245; email: *Penniman.lyn@dol.gov.*

SUPPLEMENTARY INFORMATION:

Copies of this ***Federal Register*** *notice:* Electronic copies are available at: *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's Web page at *http://www.osha.gov.*

References and Exhibits (optional): Documents referenced by OSHA in this request for information, other than OSHA standards and **Federal Register** notices, are in Docket No. OSHA–2016–0014 (Prevention of Workplace Violence in Healthcare). The docket is available at: *http://www.regulations.gov,* the Federal eRulemaking Portal. For additional information on submitting items to, or accessing items in, the docket, please refer to the Addresses section of this RFI. Most exhibits are available at *http://www.regulations.gov;* some exhibits (*e.g.,* copyrighted material) are not available to download from that Web page. However, all materials in the dockets are available for inspection and copying at the OSHA Docket Office, Room N–3653, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC.

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I. Overview

OSHA is considering whether to commence rulemaking proceedings on a standard aimed at preventing workplace violence in healthcare and social assistance workplaces perpetrated by patients or clients. Workplace violence affects a myriad of healthcare and social assistance workplaces, including psychiatric facilities, hospital emergency departments, community mental health clinics, treatment clinics for substance abuse disorders, pharmacies, community-care facilities, residential facilities and long-term care facilities. Professions affected include physicians, registered nurses, pharmacists, nurse practitioners, physicians' assistants, nurses' aides, therapists, technicians, public health nurses, home healthcare workers, social and welfare workers, security personnel, maintenance personnel and emergency medical care personnel.

OSHA's analysis of available data suggest that workers in the Health Care and Social Assistance sector (NAICS 62) face a substantially increased risk of injury due to workplace violence. Table 1 compiles data from the Bureau of Labor Statistics' (BLS) Survey of Occupational Injuries and Illnesses (SOII). In 2014, workers in this sector experienced workplace-violence-related injuries at an estimated incidence rate of 8.2 per 10,000 full time workers, over 4 times higher than the rate of 1.7 per 10,000 workers in the private sector overall (BLS Table R8, 2015). Individual portions of the healthcare sector have much higher rates. Psychiatric hospitals have incidence rates over 64 times higher than private industry as a whole, and nursing and residential care facilities have rates 11 times higher than those for private industry as a whole. The overall rate for violence-related injuries in just the social assistance subsector was 9.8 per 10,000, and individual industries, such as vocational rehabilitation with rates of 20.8 per 10,000 full-time workers are higher. In 2014, 79 percent of serious violent incidents reported by employers in healthcare and social assistance settings were caused by interactions with patients (BLS, 2015, Table R3, p. 40).

TABLE 1—CASES OF INTENTIONAL INJURY BY OTHER PERSON(S) BY INDUSTRY SECTORS IN 2014

	Nonfatal injury cases [1]	Rate per 10,000 full time workers [2]
All Private Sector Industries	15,980	1.7
Goods Producing	260	0.1
Service Producing	15,710	2.1
Trade-Transportation-and Utilities	1,950	0.9
Leisure and Hospitality	1,160	1.2
Professional and Business Services	470	0.3
Information	40	0.2
Financial Activities	90	0.1
Other Services, Except Public Administration	80	0.3
Educational and Health Services	11,920	7.7
Educational Services	810	4.4
Health Care and Social Assistance	11,100	8.2
Ambulatory Healthcare Services	960	1.9
Hospitals	3,410	8.9
Nursing and Residential Care Facilities	4,690	18.7
Social Assistance	2,050	9.8

[1] BLS Table R4, 2015, *http://www.bls.gov/iif/oshwc/osh/case/ostb4370.pdf.*
[2] BLS Table R100, 2015, *http://www.bls.gov/iif/oshwc/osh/case/ostb4466.pdf.*

BLS relies on employers to report injury and illness data and employers do not always record or accurately record workplace injuries and illnesses (Ruser, 2008; Robinson, 2014; BLS, 2014). In addition, healthcare and social assistance employees may be reluctant to report incidents of workplace violence (see Section V.A.3.b below).

Surveys of healthcare and social assistance workers provide another source of data useful for describing the extent of the problem. In one survey, 21 percent of registered nurses and nursing students reported being physically assaulted in a 12-month period (ANA, 2014). The U.S. Department of Health and Human Services (HHS) National Electronic Injury Surveillance System-Work Supplement (NEISS–WORK) reported that, of the cases where healthcare workers sought treatment for workplace violence related injuries in 2011 in hospital emergency rooms, patients were perpetrators an estimated 63 percent of the time (US GAO, 2016). Other perpetrators include patients' families and visitors, and co-workers (Stokowski, 2010; BLS Data, 2013).

A survey of 175 licensed social workers and 98 agency directors in a western state found that 25 percent of social workers had been assaulted by a client, nearly 50 percent had witnessed violence in a workplace, and more than 75 percent were fearful of violent acts (Rey, 1996). A similar survey of a national sample of 633 workers randomly drawn from the National Association of Social Workers Membership Directory reported that 17.4 percent of the respondents reported being physically threatened, and 2.8 percent being assaulted. Verbal abuse was prevalent and was reported by 42.8 percent respondents (Jayaratne *et al.,* 1996).

Though non-fatal injuries predominate by a large extent, homicides accounted for 14 fatalities in healthcare and social service settings that occurred in 2014, and 10 that occurred in 2013 (BLS SOII and CFOI Data, 2011–2014).[1]

This RFI is focused on workplace violence occurring in health care and social assistance for several reasons. While workplace violence occurs in other industries, health care services and social assistance services have a common set of risk factors related to the unique relationship between the care provider and the patient or client. The complex culture of healthcare and social assistance, in which the health care provider is typically cast as the patient's advocate, increases resistance to the notion that healthcare workers are at risk for patient-related violence (McPhaul and Lipscomb, 2004). In addition, the number of healthcare and social assistance workers is likely to grow as the sector is a large and growing component of the U.S. economy.

OSHA has a history of providing guidance to employees and employers in this sector since 1996 (see Sections II and V). In addition, a body of knowledge has emerged in recent years from research about the factors that increase the risk of violence and the interventions that mitigate or reduce the risk in health care and social assistance. As a result, workplace violence is recognized as an occupational hazard for healthcare and social assistance, which, like other hazards, can be avoided or minimized when employers take appropriate precautions to reduce risk factors that have been shown to increase the risk of violence. See Section V.A.2., Worksite analysis and hazard identification, for a discussion of risk factors.

Though OSHA has no intention of including violence that is solely verbal in a potential regulation, the Agency does ask a series of questions about threats that could reasonably be expected to result in violent acts. These threats could be verbal or written, or could be marked by body language.

In order to chart the best course going forward and inform OSHA's approach to this hazard, OSHA has posed a number of detailed questions for comment throughout the RFI. To make the best decisions about OSHA's next steps in this area, the questions posed are designed to better elucidate these general subjects:

- The scope of the problem in healthcare and social assistance—frequency of incidents of workplace violence, where those incidents most commonly occur, and who is most often the victim in those incidents;
- The common risk factors that could be addressed;
- Interventions and controls that data show are working already in the field;
- The efficacy, feasibility and cost of different options.

The remainder of the RFI is organized as follows. Section II provides

[1] Many of the deaths in the healthcare setting involved a shooting, with many perpetrated by someone the worker knew, such as a domestic partner or coworker (US GAO, 2016). While such incidents often garner media attention, they are not the typical foreseeable workplace violence incidents that are associated with predictable risk factors that employers can reduce or eliminate. OSHA does not intend to address these types of incidents in any rulemaking activity.

background on the growing awareness of the problem of workplace violence in health care and social assistance, and steps taken to date by OSHA, states, and the private sector. Section III discusses and seeks information on definitional issues. Section IV provides an overview of current data on the problem of workplace violence in the health care and social assistance sectors, and seeks input on a potential scope for a standard. Using OSHA's workplace violence guidelines as a starting point, Section V discusses the elements of a workplace violence prevention program that might be included in a standard, and asks for public input on these elements. Finally, Section VI seeks input on costs and economic impacts, and Section VII contains the references relied on by OSHA in preparing this RFI.

II. Background

A. OSHA's Prior Actions To Protect Healthcare and Social Assistance Workers From Workplace Violence

1. Guidelines for Preventing Workplace Violence for Healthcare and Social Assistance

Protecting healthcare and social assistance workers from workplace violence is not a new focus for OSHA. In 1996, OSHA published the first version of its ''Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers.'' The same year, NIOSH published and broadly disseminated its document describing violence as an occupational hazard in the healthcare workplace, as well as risk factors and prevention strategies for mitigating the hazard (NIOSH, 1996). In 2002, NIOSH published a report entitled ''Violence: Occupational Hazards in Hospitals'' (NIOSH, 2002). The current revision of OSHA's violence prevention guidelines (2015) is at: *http://www.osha.gov/Publications/osha3148.pdf.*

OSHA's Guidelines are based on industry best practices and feedback from stakeholders, and provides recommendations for policies and procedures to eliminate or reduce workplace violence in a range of healthcare and social services settings. Information on five settings was included in the updated guidelines: Hospital settings, residential treatment settings, non-residential treatment/services settings, community care settings, and field work settings. In addition, the updated 2015 version covers a broader spectrum of workers in comparison with previously published guidelines because healthcare is increasingly being provided in other settings such as nursing homes, free-standing surgical and outpatient centers, emergency care clinics, patients' homes, and pre-hospitalization emergency care settings.

The Guidelines recommend a comprehensive violence prevention program that consists of five core elements or ''building blocks'': (1) Management commitment and employee participation; (2) worksite analysis; (3) hazard prevention and control; (4) safety and health training; and (5) recordkeeping and program evaluation. These elements are discussed further in Section V below. While these guidelines provide much detailed, research-based information on specific controls and strategies for various healthcare and social assistance settings to help employers and employees prevent violence, they are recommendations and therefore non-mandatory.

Lipscomb and colleagues (2006) report the results of a participatory intervention study that implemented and then evaluated violence prevention programs that were based on the 1996 OSHA Guidelines in three New York state mental health facilities. The New York State Office of Mental Health (OMH), working through its labor-management health and safety committee established a policy requiring all 26 in-patient OMH facilities to develop and implement a proactive violence-prevention program. Recognizing the opportunity for a ''natural'' experiment, the study investigators chose three ''intervention'' and ''comparison'' sites, with the intervention sites benefitting from consultation with the study team and with the project's New York State-based violence-prevention coordinator. The intervention had three main components: (1) Implementation of a facility-specific violence prevention program; (2) conducting a risk assessment; and (3) designing and implementing feasible recommendations evolving from the risk assessment. The OSHA elements of management commitment and employee involvement, worksite analysis, hazard control and prevention, and training were operationalized within the project. The authors stated that the guideline's emphasis on management commitment and employee involvement was critical to the successful implementation of the program. Program impact was evaluated through focus groups and surveys. A comparison of pre- and post-intervention survey data indicate an improvement in staff perception of the quality of the facility's violence-prevention program (*i.e.,* OSHA elements) in both intervention and comparison facilities.

In 2015, OSHA also published a complementary Web page, ''Caring for Our Caregivers: Strategies and Tools for Workplace Violence Prevention in Healthcare'' containing resources and tools to help healthcare facilities develop and implement a workplace violence prevention program, located at: *https://www.osha.gov/dsg/hospitals/workplace_violence.html.* The focus of this guidance is primarily hospitals and behavioral health facilities, and the content was developed from examples shared with OSHA by healthcare facilities with various components of successful violence prevention programs.

2. Enforcement Directive

Although OSHA has no standard specific to the prevention of workplace violence, the Agency currently enforces Section 5(a)(1) (General Duty Clause) of the OSH Act against employers that expose their workers to this recognized hazard. Section 5(a)(1) states that employers have a general duty to furnish to each of its employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees (29 U.S.C. 654(a)(1)). Section 5(a)(1) does not specifically prescribe how employers are to eliminate or reduce their employees' exposure to workplace violence. A standard on workplace violence would help clarify employer obligations and the measures necessary to protect employees from such violence.

To prove a violation of the General Duty Clause, OSHA must provide evidence that: (1) the employer failed to keep the workplace free of a hazard to which its employees were exposed; (2) the hazard was recognized; (3) the hazard was causing or likely to cause death or serious injury; and (4) a feasible and useful method was available to correct the hazard.

Prior to 2011, federal OSHA rarely used the General Duty Clause to inspect and cite healthcare and social assistance facilities for the hazard of workplace violence, in part because no guidance existed on how to conduct such an inspection. In September 2011, OSHA took an important step toward beginning to address workplace violence in healthcare and other high-risk settings by publishing a compliance Directive CPL 02–01–052 (*https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-01-052.pdf*), detailing potential hazards in those settings and providing OSHA compliance officers with

enforcement guidance to respond to complaints regarding the hazard of workplace violence. The Directive provides guidance on how a workplace violence enforcement case should be developed and what steps Area Offices should take to assist employers in addressing this hazard. The Agency is currently in the process of updating and revising its Directive.

A relatively small percentage of the inspections related to workplace violence in health care facilities resulted in general duty clause citations. From 2011 through 2015, OSHA inspected 107 hospitals (NAICS code 622) and nursing and residential care facilities (NAICS code 623) and issued 17 general duty clause citations to healthcare employers for failing to address workplace violence (OSHA Enforcement Data).

B. State Laws

As of August 2015, nine states had enacted laws that require employers who employ healthcare and/or social assistance workers to establish a plan or program to protect those workers from workplace violence: California, Connecticut, Illinois, Maine, Maryland, New Jersey, New York, Oregon, and Washington (US GAO, 2016). State laws differ widely in definitions of workplace violence, requirements and scopes of facilities covered. For example, Washington and New Jersey cover the healthcare sector broadly, while Maine covers only hospitals and Illinois covers only developmental disabilities and mental health centers. Eight state laws require worksite risk assessment to identify hazards that may lead to violent incidents; however, not all state regulations specify how to conduct a risk assessment. Only Maine does not have a requirement for a risk assessment. All the states but Maine also require violence prevention training, although requirements differ in frequency and format of training, as well as the occupations of the employees required to be trained. All nine states require healthcare employers to record incidents of violence against workers. Some laws apply specifically to healthcare settings (*e.g.,* Washington Labor and Industries' RCW 49.19), while others apply more broadly to cover additional industries or sectors. New York is the only state that operates its own OSHA program that has a standard that specifically requires a violence prevention program; however, coverage is limited to public employees. California law requires hospitals to conduct security and safety assessments, and to use the assessment to develop and update a security plan (California Health and Safety Code Section 1257.7). Also, as of 1991, Cal/OSHA's Workplace Injury and Illness Prevention standard requires a program to address and prevent known occupational hazards, including violence.

Tragic events are often the impetus for legislation. Such was the case when a psychiatric technician was strangled on the Napa State Hospital grounds by a patient in November 2010. (*http://articles.latimes.com/2010/nov/03/local/la-me-hospital-violence-20101103).* In February 2014, two healthcare worker unions, the Service Employees International Union (SEIU) and SEIU Nurse Alliance of California, filed petitions requesting the California Occupational Safety and Health Standards Board to adopt a new standard that would provide more protections to healthcare workers, specifically against workplace violence.

In June 2014, California's Board requested the Division of Occupational Safety and Health to convene an advisory committee and develop a proposal for workplace violence protection standards. In September 2014, the governor signed Senate Bill (SB) 1299, requiring the Board to adopt standards developed by the Division that would require facilities to adopt a workplace violence prevention plan as part of their injury and illness prevention plan. On October 20, 2016, California announced the adoption of those standards, and became the first state to promulgate an occupational health and safety standard requiring healthcare facilities to take certain specific steps to establish, implement and maintain an effective workplace violence prevention plan. Implementation will begin in 2017.

Some studies in the published literature evaluated whether healthcare facilities located in states with state laws have higher quality violence prevention programs than in states with no requirements, as a measure of the value or efficacy of state laws (Peek-Asa *et al.,* 2007; Peek-Asa *et al.,* 2009, Casteel *et al.,* 2009). Peek-Asa *et al.* (2007) compared workplace violence programs in high-risk emergency departments among a representative sample of hospitals in California (a state with a violence prevention law) and New Jersey (which at the time of the study did not have such a law). California had significantly higher scores for training, policies and procedures, but there was no difference in the scoring for security and environmental approaches. Program component scores were not highly correlated. For example, hospitals with a strong training program were not more likely to have strong policies and procedures. The authors concluded that a comprehensive approach that coordinates the components of training, policies, procedures, environmental approaches, and security is likely to be achieved only through multidisciplinary and representative input from the staff and management (Peek-Asa *et al.,* 2007).

Two years later, the same authors (Peek-Asa *et al.,* 2009) conducted studies that compared workplace violence programs in a representative sample of psychiatric units and facilities in California and New Jersey. The researchers found that a similar proportion of hospitals in both states had workplace violence prevention training programs. A higher proportion of hospitals in California had written workplace violence policies and a higher proportion of New Jersey hospitals had implemented environmental and security modifications to reduce violence.

One study examined the effects of a state law on workers' compensation costs, and supports the conclusion that Washington State's efforts to reduce workplace violence in the healthcare industry have led to lower injury rates and workers' compensation costs. From 1997 to 2007, the state's average annual rate of workers' compensation claims associated with workplace violence in the healthcare and social assistance industry was 75.5 per 10,000 full-time equivalent workers (FTEs). From 2007 to 2013, the rate had fallen to 54.5 claims per 10,000 FTEs, a decrease of 28 percent. This improvement coincides with Washington's 2009 rule that required hazard assessments, training, and incident tracking for workplace violence (Foley, and Rauser, 2012).

C. Recommendations From Governmental, Professional and Public Interest Organizations

In response to a request from members of Congress, the GAO conducted an investigation of OSHA's efforts to protect healthcare workers from workplace violence in healthcare. The investigation focused on healthcare, and included residential care facilities and home health care services.

During its investigation, GAO identified nine states with workplace violence prevention requirements for healthcare employers, examined workplace violence incidents, conducted a literature review, and interviewed OSHA and state officials. The final report, published in April 2016, included a summary of interviews of healthcare workers, who described a

range of violent encounters with patients. See the table below for details.

TABLE 2—EXAMPLES OF WORKPLACE VIOLENCE INCIDENTS REPORTED BY THE HEALTH CARE WORKERS GAO INTERVIEWED

Health care facilities	Examples of reported workplace violence incidents
Hospitals with emergency rooms	• Worker hit in the head by a patient when drawing the patient's blood and suffered a concussion and a permanent injury to the neck. • Worker knocked unconscious by a patient when starting intravenous therapy on the patient.
Psychiatric hospitals	• Worker punched and thrown against a wall by a patient and had to have several surgeries. As a result of the injuries, the worker was unable to return to work. • Patient put worker in a head-lock, and worker suffered neck pain and headaches and was unable to carry out regular workload. • Patient broke healthcare worker's hand when the healthcare worker intervened in a conflict between two patients.
Residential care facilities	• Patient became upset after being deemed unfit to return home and attacked the worker. • Worker hit in the head by a patient and suffered both physical and emotional problems as a result of the incident.
Home health care services	• Worker attacked by patient with dementia and had to defend self. • Worker was sexually harassed by a patient when the patient grabbed the worker while rendering care.

Source: GAO, Workplace Safety and Health: Additional Efforts Needed to Help Protect Healthcare Workers from Workplace Violence, 2016.

In its final report, the GAO recommended that OSHA provide additional information to assist inspectors in developing citations, develop a policy for following up on hazard alert letters concerning workplace violence hazards in healthcare facilities, and assess the results of its efforts to determine whether additional action, such as development of a standard, may be needed. OSHA agreed with the GAO's recommendations and stated that it would take action to address them. Since then, OSHA's Training Institute in the Directorate of Training and Education developed a course on Workplace Violence Investigations for its Compliance Safety and Health Officers (CSHOs) and other staff with responsibilities in this area. In June 2016, approximately 30 CSHOs, Area Directors, Acting Area Directors, and other OSHA staff, participated in the first offering of the 3-day course on workplace violence, which included exercises using actual scenarios encountered by investigators. The Agency's publication of this RFI is in part a response to the GAO's recommendation to consider issuance of a standard addressing workplace violence. OSHA will review the record developed as a result of the information received and decide on the appropriate course of action regarding a standard.

In July 2016, a coalition of unions representing healthcare workers, including SEIU, AFL–CIO, and the American Federation of Governmental Employees, petitioned the Agency for a Workplace Violence Prevention Standard. National Nurses United (NNU) filed a similar petition. While NNU petitioned the Agency for a standard covering its membership only (healthcare workers), the broader coalition of labor unions requested a standard covering all workers in healthcare and social assistance. By this time, the Agency had already made the public aware about the publication of an RFI by November 2016, via the Unified Regulatory Agenda.

In recent years, several nursing professional associations have published statements on workplace violence (ANA, 2015; APNA, 2008; ENA, 2010). In addition, the ANA has published a model state law, ''The Violence Prevention in Health Care Facilities Act,'' recommending that healthcare facilities establish violence prevention programs to protect healthcare workers from acts of violence (ANA, 2011).

Some organizations have recommended specific programmatic elements, policies, procedures and processes to reduce and prevent workplace violence. In 2008, APNA published recommendations for addressing workplace violence. In 2011, it published a report that included recommendations for adequate staffing, increased security, video monitoring, and safe areas for nurses (Cafaro, 2012; *http://www.apna.org/i4a/pages/index.cfm?pageID=4912#sthash.2JKbjy3w.dpuf).* The American Association of Occupational Health Nurses, Inc. has published strategies for preventing workplace violence. It also noted the problem of underreporting of workplace violence events, which it recommended should be addressed so that ''the scope of non-fatal violence in the workplace'' is adequately measured and in turn ''informed targeted prevention strategies'' are developed (AAOHN, 2015).

In 2013, Public Citizen published ''Health Care Workers Unprotected; Insufficient Inspections and Standards Leave Safety Risks Unaddressed,'' which recommended that OSHA promulgate a standard to address the hazardous situations of workplace violence. Based on their analysis of data from the Bureau of Labor Statistics, the U.S. Census Bureau, OSHA, the AFL–CIO, and The Kaiser Family Foundation, they recommended that such a standard should require employers to create a policy of zero tolerance for workplace violence, including verbal and nonverbal threats; require workplace policies that encourage employees to promptly report incidents and suggest ways to reduce or eliminate risks; provide protections to employees to deter employers from retaliating against those who report workplace-violence incidents; and require employers to develop a comprehensive plan for maintaining security in the workplace (Public Citizen, 2013).

The Society for Human Resource Management's (SHRM) Workplace Violence Policy provides guidance on prohibited conduct, reporting procedures, risk reduction measures, employees at risk, dangerous/emergency situations, and enforcement for human resource professionals.

D. Questions for Section II

The following questions are intended to solicit information on the topics covered in this section. In general, OSHA is interested in hearing about healthcare facilities' experiences with

provisions of state laws that have been shown to be effective in some way. Wherever possible, please indicate the title of the person completing the question and the type and the number of employees at your facility. OSHA is also interested in hearing from employers and managers in public sector facilities in New York State about their experiences with the Public Employees Safety and Health workplace violence prevention regulations.

Question II.1: What state are you employed in or where is your facility located? If your state has a workplace violence law, what has been your experience complying with these requirements? Are there any specific provisions included in your workplace violence law that you think should or should not be included in an OSHA standard? If so, what provisions and why?

Question II.2: For employers and managers: If your state has a workplace violence prevention law, have you or are you conducting an evaluation of the effectiveness of its programs or policies? If you are conducting such an analysis, how are you doing it? Have you been able to demonstrate improved tracking of workplace violence incidents and/or a change in the frequency or severity of violent incidents? If you think it is effective, please explain why. If you think it is ineffective, please explain why.

Question II.3: If your state has workplace violence prevention laws, how many hours do you spend each year (month) complying with these laws?

Question II.4: Please specify the number or percentage of staff participating in workplace violence prevention activities required under your state laws.

Question II.5: Do you have experience implementing any of the workplace violence prevention practices recommended by the American Psychiatric Nurses Association (APNA), American Association of Occupational Health Nurses (AAOHN), or similar organizations? If so, please discuss the resources it took to implement the practice, and whether you think the practice was effective. Please provide any data you have to support your conclusions.

III. Defining Workplace Violence

A. Definition and Types of Events Under Consideration

As discussed in the overview above, the data show that injuries and fatalities in the health care and social assistance sector due to workplace violence are substantially elevated compared to the private sector overall. This section addresses the question of how to define the universe of workplace violence that OSHA might cover in a standard. This involves at least two issues: (1) What events constitute ''violence'' (*i.e.,* should physical assaults be covered only, or should threats be considered as well?); and (2) should there be consideration of the type of injury (physical, psychological) and a threshold for harm that could be sustained as a result of the activity.

The National Institute of Occupational Safety and Health (NIOSH) defines workplace violence as ''violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty'' (*https://www.cdc.gov/niosh/docs/2002-101/*). Examples of violence include threats (expressions of intent to cause harm, including verbal threats, threatening body language, and written threats), physical assaults (attacks ranging from slapping and beating to rape, homicide, and the use of weapons such as firearms, bombs, or knives), and muggings (aggravated assaults, usually conducted by surprise and with intent to rob) (NIOSH at: *http://www.cdc.gov/niosh/docs/2002-101/default.html*). OSHA's Web page refers to ''workplace violence'' as any act or threat of physical violence, harassment, intimidation, or other threatening disruptive behavior that occurs at the work site. Both the NIOSH definition and the general one on OSHA's Web site include harassment and intimidation; however, OSHA's focus has been solely on physical injuries resulting in serious harm. The effects of violence on individuals represent a range in intensity and include minor physical injuries; serious physical injuries; temporary and permanent physical disability; psychological trauma; and death. Healthcare and social assistance workers involved in workplace violence incidents can suffer physical injury, disability, and chronic pain; employees who experience violence also suffer psychological problems such as loss of sleep, nightmares, and flashbacks (Gerberich *et al.,* 2004).

Further, workplace violence can be classified into the following four categories, based on the relationship between the perpetrator and the victim/worker: Type I (criminal intent; the perpetrator has no legitimate relationship to the business), Type II (customer/client/patient), Type III (worker-on-worker), and Type IV (personal relationship) (UIIPRC, 2001). Type II events occur most commonly in healthcare and social assistance and these events are the type addressed by this RFI. Type III (sometimes referred to as ''lateral violence'') is also commonly reported in the literature, especially when taking verbal abuse into account.

OSHA intends to address only Type II, or customer/client/patient violence in this RFI. Type I, or criminal intent, perpetrated by criminals with no connection to the workplace other than to commit a crime, typically does not apply the healthcare environment. OSHA does not intend to seek information specific to Type I or Type III incidents, ''lateral'' or ''worker-on-worker'' violence. In addition, OSHA does not intend to cover Type IV incidents or violence that happen to be carried out in a healthcare workplace but are based on personal relationships. Although such incidents often garner media attention, they are not the typical foreseeable workplace violence incidents that are associated with predictable risk factors in the workplace that employers can reduce or eliminate. OSHA has determined that Type I, III and IV incidents are generally outside the scope of any potential rulemaking activity stemming from this RFI.

B. Questions for Section III

The following questions are intended to solicit information on the topics covered in this section. Wherever possible, please indicate the title of the person providing the information and the type and number of employees of your healthcare and/or social assistance facility or facilities.

Question III.1: CDC/NIOSH defines workplace violence as ''violent acts (including physical assaults and threats of assaults) directed toward persons at work or on duty'' (CDC/NIOSH, 2002). Is this the most appropriate definition for OSHA to use if the Agency proceeds with a regulation?

Question III. 2: Do employers encourage reporting and evaluation of verbal threats? If so, are verbal threats reported and evaluated? If evaluated, how do employers currently evaluate verbal threats (*i.e.,* who conducts the evaluation, how long does such an evaluation take, what criteria are used to evaluate verbal threats, are such investigations/evaluations effective)?

Question III.3: Though OSHA has no intention of including violence that is solely verbal in a potential regulation, what approach might the Agency take regarding those threats, which may include verbal, threatening body language, and written, that could reasonably be expected to result in violent acts?

Question III.4: Employers covered by OSHA's recordkeeping regulation must

record each fatality, injury or illness that is work-related, that is a new case and not a continuation of an old case, and meets one or more of the general recording criteria in section 1904.7 or the additional criteria for specific cases found in section 1904.8 through 1904.11. A case meets the general recording criteria in section 1904.7 if it results in death, loss of consciousness, days away from work or restricted work or job transfer, or medical treatment beyond first aid. What types of injuries have occurred from workplace violence incidents? Do these types of injuries typically meet the OSHA criteria for recording the injury on the 300 Log?

Question III.5: Currently, a mental illness sustained as a result of an assault in the workplace, *e.g.,* Posttraumatic Stress Disorder (PTSD), is not required to be recorded on the OSHA 300 Log ''unless the employee voluntarily provides the employer with an opinion from a physician or other licensed healthcare professional with appropriate training and experience (psychiatrist, psychologist, psychiatric nurse practitioner, etc.) stating that the employee has a mental illness that is work-related (1904.5(b)(2)(ix)).'' Although protecting the confidentiality of the victim is important, an unintended consequence of omitting these incidents from the 300 Log is that the extent of the problem is likely underestimated. In a workplace violence prevention standard, should this exclusion be maintained or be removed? Is there a way to capture the information about cases, while still protecting confidentiality?

Question III.6: Are you aware of cases of PTSD or psychological trauma related to workplace violence in your facility? If so, was it captured in the recordkeeping system and how? Please provide examples, omitting personal data and information.

Question III.7: Are there other indicators of the extent and severity of workplace violence in healthcare or social assistance that OSHA has not captured here? Please provide any additional data that you are aware of, or any indicators you have used in your workplace to address workplace violence.

IV. Scope

A. Health Care and Social Assistance

The Health Care and Social Assistance sector is composed of a wide range of establishments providing varying levels of healthcare and social assistance services, from general medical-surgical hospitals to at-home patient care to treatment facilities for substance abuse disorders, and different types of establishments providing social assistance, such as child day care services, vocational rehabilitation and food to the needy. In 2015 the healthcare industry had a total of 1,432,801 establishments and employed 18,738,870 workers in both healthcare and non-healthcare occupations (BLS, Census of Employment and Wages, 2016 and Occupational Employment Statistics, 2015). The Health Care and Social Assistance sector provides a range of services employing a diverse group of occupations at places such as: Nursing homes, free-standing surgical and outpatient centers, emergency care clinics, patients' homes, and pre-hospitalization emergency care settings. The largest occupational group employed in the Health Care and Social Assistance industry are healthcare practitioners (defined as healthcare professionals, technicians, and healthcare support workers), which included 6,288,040 workers in 2015, an increase of 1.2 million workers over the past 10 years (BLS, Occupational Employment Statistics, 2016). Healthcare practitioners are employed across various industries, but the industry with the largest concentration of healthcare practitioners is General Medical and Surgical Hospitals, which employed 2,926,350 workers in 2015.

TABLE 3—TOP 5 OCCUPATIONS IN HEALTHCARE AND SOCIAL ASSISTANCE INDUSTRY BETWEEN 2005 AND 2015

	2005 (million)	2015 (million)
Healthcare and social assistance industry	15.2	18.7
Healthcare practitioners and technical occupations	5.1	6.3
Healthcare support occupations	2.9	3.5
Office and administrative support occupations	2.5	2.7
Personal care and service occupations	1.0	1.9
Community and social services occupations	0.8	1.0

BLS, Occupational Employment Statistics, April 2016.

Across all industries there were 8.0 million Health Care Practitioners and Technical workers employed in 2015 and can be found in various parts of the private sector outside of the Health Care and Social Assistance sector, for example in Air Transportation, Accommodations, Recreation, and Retail Trade. Of the almost 8.0 million Healthcare Practitioners and Technical workers, 515,970 are employed at retail trade facilities, the majority are specifically at Health and Personal Care Stores.

For purposes of assessing workplace violence risk, OSHA has used the BLS category of Intentional Injury by Other Person. OSHA has not included here the BLS category of Injury by Person—Unintentional or Intent Unknown. That category may include some incidents classifiable as workplace violence, but also includes large numbers of injuries resulting from such causes like attempting to lift patients. Unintentional injuries resembling workplace violence may also be common in mental health services. Of the almost 16,000 cases of Intentional Injury by Other Persons in the private sector in 2014, 11,100 were in the Healthcare and Social Assistance sector (BLS Table R4, November 2015).

The rate of intentional injury in the Healthcare and Social Assistance sector as a whole was 8.2 per 10,000 full time workers, over four times the rate across all private industry, 1.7 per 10,000 full-time workers in 2014 (BLS Table R8, November 2015). Within the Healthcare and Social Assistance sector, the incident rates for Intentional Injury by Other Person(s) ranges from a low of 0.4 per 10,000 full-time workers in Offices of Physicians (lower than private industry as a whole) to a high of 109.5 per 10,000 full-time workers in Psychiatric and Substance Abuse Hospitals [2] (BLS Table R8, November 2015). Of the four major subsectors within Health Care and Social Assistance in 2014, the highest incident rate of Intentional Injury by Other Person(s) was 18.7 per 10,000 in Nursing and Residential Care Facilities.

[2] The term ''Substance Abuse Hospital'' is used because it is the official designation in the NAICS code manual for such facilities.

The incident rates for the next two highest subsectors, Hospitals, and Social Assistance were half that of Nursing and Residential Care Facilities, 8.9 and 9.8 respectively. The subsector of Nursing and Residential Care Facilities includes establishments providing services to a diverse population of patients, many of whom need a higher level of care at these facilities. In contrast, the services provided in the other areas of the Health Care and Social Assistance sector may typically involve more routine health care services requiring less physically demanding care from staff. This wide range reflects the diversity of workplace conditions and patient interactions faced by workers in the Health Care and Social Assistance economic sector.

TABLE 4—INCIDENT RATE FOR VIOLENCE AND OTHER INJURIES BY PRIVATE INDUSTRY IN THE UNITED STATES PER 10,000 FULL TIME WORKERS IN 2014

	Intentional injury by other person
All Private Industry	1.7
Health care and social assistance	8.2
Ambulatory health care services	1.9
Offices of physicians	0.4
Offices of physicians except mental health	0.3
Offices of mental health physicians	8.5
Offices of other health practitioners	—
Outpatient care centers	4.1
Medical and diagnostic laboratories	5.6
Home health care services	5.0
Other ambulatory health care services	3.1
Ambulance services	5.3
All other ambulatory health care services	—
Hospitals	8.9
General medical and surgical hospitals	6.7
Psychiatric and substance abuse hospitals	109.5
Other hospitals	7.3
Nursing and residential care facilities	18.7
Nursing care facilities	15.8
Residential mental health facilities	34.9
Community care facilities for the elderly	7.2
Other residential care facilities	39.9
Social assistance	9.8
Individual and family services	10.2
Child and youth services	4.0
Services for the elderly and disabled	11.0
Emergency and other relief services	—
Community housing services	—
Vocational rehabilitation services	20.8
Child day care services	6.5

(BLS Table R8, November 2015).
Note: Dash indicates data do not meet BLS publication guidelines for their Survey of Occupational Injuries and Illnesses.

The industries in the Social Assistance subsector provide a wide variety of services directly to clients, and include industries with incident rates of intentional injury that are higher than those in the Ambulatory Health Care sector. The highest incident rate within this sector for intentional injury by other person was in Vocational Rehabilitation Services with 20.8 per 10,000 full time workers in 2014. The next highest industry in this sector was Services for the Elderly and Disabled with an incident rate of 11 per 10,000 full time workers. This sector includes, among other industries, services for children and youth, the elderly, and persons with disabilities; community food and housing services; vocational rehabilitation; and day care centers. Consequently, the risk of workplace violence to healthcare workers differs depending on the nature of the setting and the level of interaction with patients.

The severity of workplace violence in the Health Care and Social Assistance sector is even greater in state government entities where the incident rate for intentional injury by other person(s) in 2014 was 79.3 per 10,000 full time workers. Across state government sectors the incident rate for intentional injury by other persons in the Health Care and Social Assistance sector is the highest even compared to the sector for Public Administration at 10.5 per 10,000 full time workers, which includes Police Protection and Correctional Institutions. State-run healthcare facilities often serve individuals with fewer available heath care options and populations with fewer preventive healthcare services. State-run healthcare and social assistance facilities may face unique challenges compared to the private sector.

TABLE 5—INCIDENT RATE FOR VIOLENCE AND OTHER INJURIES BY SELECT STATE INDUSTRIES IN THE UNITED STATES PER 10,000 FULL TIME WORKERS IN 2014

	Intentional injury by other person
ALL STATE GOVERNMENT	15.8
SERVICE PROVIDING	16.2
Healthcare and Social Assistance	79.3
Hospitals	97.4
Nursing and Residential Care Facilities	116.8
Public Administration	10.5
Justice, Public Order, and Safety Activities	23.1
Police Protection	8.7
Correctional Institutions	37.2

BLS Table S8, April 2016.

Locally-run health care and social assistance facilities, on the other hand, appear to present risks that are comparable to private facilities, the incident rate of intentional injury by other persons in sector of Healthcare and Social Assistance was 13.1 per 10,000 full time workers. The overall incident rate for the Public Administration sector in local governments is not much lower at 11.1 per 10,000 full time workers.

TABLE 6—INCIDENT RATE FOR VIOLENCE AND OTHER INJURIES BY SELECT LOCAL GOVERNMENT INDUSTRIES IN THE UNITED STATES PER 10,000 FULL TIME WORKERS IN 2014

	Intentional injury by other person
ALL LOCAL GOVERNMENT	8.7
SERVICE PROVIDING	8.8
Healthcare and Social Assistance	13.1
Hospitals	13.0
Nursing and Residential Care Facilities	39.9
Public Administration	11.1
Justice, Public Order, and Safety Activities	22.5
Police Protection	36.8
Fire Protection	7.1

BLS Table L8, April 2016.

Another way to consider the data is by occupation. Nursing-Psychiatric and Home Health Aides (which includes Psychiatric Aids and Nursing Assistants) had the highest rates of violence in 2014 across three of the four sectors. Out of the 4,690 injury cases in Nursing and Residential Care Facilities (based on data from BLS provided upon request), 2,640 of the cases of workplace violence were perpetrated against Nursing-Psychiatric and Home Health Aides in 2014 (BLS SOII 2014 Data, requested June 2016). Across all private industries, the highest rates of incidents for Intentional Injury by Other Person(s) were for Psychiatric Aides at 426.4 per 10,000 full time workers, followed by Psychiatric Technicians at 206.8 per 10,000 full time workers in 2014 (BLS Table R100, November 2015). These two occupations reflect the highest rates of intentional injury by other person(s) that occurs in the major sector of healthcare practitioners and technical occupations.

TABLE 7—CASES OF INTENTIONAL INJURY BY OTHER PERSON(S) BY INDUSTRY AND OCCUPATION IN 2014

	2014
All Private Sector Industries	15,980
Goods Producing	260
Service Producing	15,710
Healthcare and Social Assistance	11,100
Ambulatory Healthcare Services	960
Counselors- Social Workers- and Other Community and Social Service Specialists	100
Health Diagnosing and Treating Practitioners	150
Health Technologists and Technicians	230
Nursing- Psychiatric- and Home Health Aides	290
Occupational Therapy and Physical Therapist Assistants and Aides	—
Other Personal Care and Service Workers	100
Hospitals	3,410
Counselors- Social Workers- and Other Community and Social Service Specialists	180
Health Diagnosing and Treating Practitioners	1,110
Health Technologists and Technicians	610
Other Healthcare Practitioners and Technical Occupations	20

TABLE 7—CASES OF INTENTIONAL INJURY BY OTHER PERSON(S) BY INDUSTRY AND OCCUPATION IN 2014—Continued

	2014
Nursing- Psychiatric- and Home Health Aides	1,030
Occupational Therapy and Physical Therapist Assistants and Aides	—
Other Personal Care and Service Workers	100
Nursing and Residential Care Facilities	4,690
Counselors- Social Workers- and Other Community and Social Service Specialists	370
Health Diagnosing and Treating Practitioners	170
Health Technologists and Technicians	310
Nursing- Psychiatric- and Home Health Aides	2,640
Occupational Therapy and Physical Therapist Assistants and Aides	—
Other Personal Care and Service Workers	770
Social Assistance	2,050
Counselors- Social Workers- and Other Community and Social Service Specialists	190
Health Diagnosing and Treating Practitioners	30
Health Technologists and Technicians	—
Nursing- Psychiatric- and Home Health Aides	150
Other Personal Care and Service Workers	1,060

BLS SOII 2014 Data, requested June 2016.
Note: Dash indicates data do not meet BLS publication guidelines for their Survey of Occupational Injuries and Illnesses.

Violence in the workplace is a topic that has been studied heavily using different data sources such as workers' compensation data, and occupation specific surveys. The results from these studies highlight similar findings to that of BLS's SOII data by industry, both showing that workplace injury rates of workers in the healthcare industry rank among the highest across private sector industries. In one study, Washington State workers compensation data was evaluated for the period between 1997 and 2007 (Foley, and Rauser, 2012). The results showed that the industry sectors with the highest rates of workplace violence were Health Care and Social Assistance (75.5 claims per 10, 000 FTEs), Public Administration (29.9 per 10,000 FTEs), and Educational Services (15.0 claims per 10,000 FTEs). Within the Health Care and Social Assistance sector, the industry groups with the highest estimated claim rates were Psychiatric and Substance Abuse Hospitals [3] at 875 per 10,000 FTEs, and Residential Mental Retardation, Mental Health and Substance Abuse Facilities at 749 per 10,000 FTEs. The rates of these two Health Care and Social Assistance groups are 65 times and 56 times the overall claim rate of 13.4 per 10,000 FTEs for workplace violence in all industries. A study that surveyed staff in a psychiatric hospital (Phillips, 2016) found that 70 percent of staff reported being physically assaulted within the last year. Another study that surveyed over 300 staff in a psychiatric hospital found that ward staff, which had the highest levels of patient contact, were more likely than clinical care and supervisory workers to report being physically assaulted by patients (Kelly and Subica, 2015; as reported in US GAO, 2016). Data from HHS' NEISS-Work data set showed that in 2011 the estimated rate of nonfatal workplace violence injuries for workers in healthcare facilities was statistically greater than the estimated rate for all workers. The Department of Justice's National Crime Victimization Survey (NCVS) data set showed that from 2009 through 2013 healthcare workers experienced workplace violence at more than twice the estimated rate for all workers (after accounting for the sampling error). These results consistently point to the healthcare industry and occupations within the healthcare field as having the highest risks to workplace violence compared to other private sector industries.

The four subsectors that make up the Health Care and Social Assistance sector include a wide range of establishments providing varying types of services to the general public, and placing workers at elevated levels of exposure to workplace violence relative to other economic sectors. The Health Care and Social Assistance sector includes industries with the highest rates for Intentional Injury by Other Persons exceeding all other private sector industries.

B. Questions for Section IV

The following questions are intended to solicit information on the topics covered in this section. Wherever possible, please indicate the title of the person completing the question and the type and employee size of your healthcare and/or social assistance facility.

Question IV.1: Rates of workplace violence vary widely within the healthcare and social assistance sector, ranging from extremely high to below private industry averages. How would you suggest OSHA approach the issue of whom should be included in a possible standard? For example, should the criteria for consideration under the standard be certain occupations (*e.g.,* nurses), regardless of where they work? Or is it more appropriate to include all healthcare and social assistance workers who work in certain types of facilities (*e.g.,* in-patient hospitals and long-term care facilities)? Another approach could be to extend coverage to include all employees who provide direct patient care, without regard to occupation or type of facility. If OSHA were to take this approach, should home healthcare be covered?

Question IV.2: If OSHA issues a standard on workplace violence in healthcare, should it include all or portions of the Social Assistance subsector? Are the appropriate preventive measures in this subsector sufficiently similar to those appropriate to healthcare for a single standard addressing both to make sense?

Question IV.3: The only comparative quantitative data provided by BLS is for lost workday injuries. OSHA is particularly interested in data that could help to quantitatively estimate the extent of all kinds of workplace violence problems and not just those caused by lost workday injuries. For that reason, OSHA requests information and data on both workplace violence incidents that resulted in days away from work needed to recover from the injury as well as those that did not require days away from work, but may have required only first aid treatment.

[3] The term ''Substance Abuse Hospital'' is used because it is the official designation in the NAICS code manual for such facilities.

Question IV.4: OSHA requests information on which occupations are at a higher risk of workplace violence at your facility and what about these occupations cause them to be at higher risk. Please provide the job titles and duties of these occupations. Please provide estimates on how many of your workers are providing direct patient care and the proportion of your workforce this represents.

Question IV.5: The GAO Report relied on BLS SOII data, HHS NEISS data and DOJ NCVS data. Are there any other data sets or data sources OSHA should obtain for better estimating the extent of workplace violence?

Question IV.6: The data provided by BLS are for relatively aggregated industries. Instance of high risk of workplace violence can be found aggregated with industries with low average risk, and low risk of workplace violence within industries with high risk. Please describe if your establishment's experience with workplace violence is consistent with the relative risks reported by BLS in the tables found in this section? If you are in an industry with high rates, are there places within your industry where establishments or kinds of establishments have lower rates than the industry as a whole? If you are in an industry with relatively low rates, are there work stations within establishments or within the industry that have higher rates?

Question IV.7: Are there special circumstances in your industry or establishment that OSHA should take into account when considering a need for a workplace violence prevention standard?

Question IV.8: Please comment if the workplace violence prevention efforts put in place at your establishments are specific to certain settings or activities within the facility, and how they are triggered.

Question IV.9: OSHA has focused on the Health Care and Social Assistance sectors in this RFI. However, workers who provide healthcare and social assistance are frequently found in other industries. Should a potential OSHA standard cover workers who provide healthcare or social assistance in whatever industries they work?

V. Workplace Violence Prevention Programs; Risk Factors and Controls/Interventions

A. Elements of Violence Prevention Programs

OSHA has recognized the unique challenges of workplace violence in healthcare and social assistance for decades. OSHA's ''Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers,'' which was last updated in 2015 is based on industry best practices and feedback from stakeholders, provides recommendations for policies and procedures to eliminate or reduce workplace violence in a range of healthcare and social assistance settings. The guidelines recommend a comprehensive violence prevention program that covers the following five core elements: (1) Management commitment and worker participation; (2) worksite analysis and hazard identification; (3) hazard prevention and control; (4) safety and health training; and (5) recordkeeping and program evaluation. Below, OSHA uses this framework in discussing and seeking information on the elements that might be included in a workplace violence standard. In addition, because there are particular concerns with underreporting of workplace violence in the healthcare and social assistance sector, below OSHA also discusses and seeks information on effectiveness of its whistleblower protection requirements in these sectors.

1. Management Commitment and Employee Participation

OSHA's Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers highlight the benefits of commitment by management and establishment of a joint management-employee committee, whether the committee is focused on workplace violence prevention or worker safety more broadly. The structure of the management-employee teams will differ based on the facility's size and the availability of personnel to staff it.

OSHA is interested in hearing from employers and individuals working in healthcare and social assistance about their experiences with management commitment and employee participation. Specific questions regarding these topics are at the end of Section V.

2. Worksite Analysis and Hazard Identification

OSHA's guidelines emphasize worksite analysis and hazard identification. A worksite analysis involves a mutual step-by-step assessment of the workplace to find existing or potential hazards that may lead to incidents of workplace violence.

Healthcare and social assistance workers face a number of risk factors that are known to contribute to violence in the workplace. Common risk factors (or factors that have been shown to increase the risk of harm if one is exposed to a hazard) for workplace violence generally fall into two groups: (1) Patient, client and setting-related and (2) organizational-related (OSHA, 2015a, p. 4–5). The patient/client and setting-related group includes: (a) Working directly with people who have a history of violence, especially if they are under the influence of drugs or alcohol or a diagnosis of dementia; (b) lifting, moving and transporting patients and clients; (c) working alone in a facility or in patients' homes; (d) poor environmental design of the workplace that may block employee vision or interfere with escape from a violent incident; poor lighting in hallways, corridors, rooms, parking lots and other exterior areas; (e) lack of means of emergency communication; (f) long waiting periods for service; or (g) working in neighborhoods with high crime rates.

Organizational risks (the second group) arise from workplace policies, or the lack thereof. Examples include a lack of facility policies and staff training for recognizing and managing escalating hostile and assaultive behaviors from patients, clients, visitors, or staff; working when understaffed, especially during mealtimes and visiting hours; inadequate security and mental health personnel on site; not permitting smoking; allowing unrestricted movement of the public in clinics and hospitals; allowing a perception that violence is tolerated and victims will not be able to report the incident to police and/or press charges; and an overemphasis on customer satisfaction over staff safety (OSHA, 2015a).

Studies show that staff working in some hospital units or areas are at greater risks than others. High-risk areas include emergency departments (EDs), admission areas, long-term care and geriatrics settings, behavioral health, waiting rooms, and obstetrics and pediatrics, among others (DeSanto *et al.,* 2013).

Assault rates for nurses, physicians and other staff working in EDs have been shown to be among the highest (Crilly *et al.,* 2004; Gerberich *et al.,* 2005; Gates *et al.,* 2006; Gacki-Smith *et al.,* 2009). In high volume urban emergency departments and residential day facilities, staff are in frequent contact with patients or family members who may have a history of violence, and/or a history of substance abuse disorders. Also, an increasing number of patients are in possession of handguns and weapons (Stokowski, 2010).

Workers in the healthcare occupations of psychiatric aides, psychiatric

technicians, and nursing assistants experienced higher rates of workplace violence compared to other healthcare occupations and workers overall (BLS Table R100, 2015; Pompeii *et al.,* 2015). Some studies have found that nursing assistants in long-term care have the highest incidence of assaults among all workers in the U.S. (Gates *et al.,* 2005).

Surveys of nurses have identified risk factors including patient mental health or behavioral issues, medication withdrawal, pain, history of a substance abuse disorder, and being unhappy with care (Pompeii *et al.,* 2015).

OSHA is interested in hearing from employers and individuals working in healthcare and social assistance about their experiences with worksite analysis and hazard identification, including how they use risk factors. Specific questions regarding these topics are at the end of Section V.

3. Hazard Prevention and Control

Once workplace violence hazards are identified, controls can be designed and implemented to prevent and control them. OSHA's hierarchy of controls includes: elimination, substitution, engineering controls, administrative controls, and work practices, and personal protective equipment (PPE) in that order. Engineering controls for workplace violence prevention are permanent changes to the work environment. Administrative controls are policies and procedures that reduce or prevent exposure to risk factors. Administrative strategies include modification of job rules and procedures, training and education, scheduling, or modifying assigned duties.

a. Engineering Controls

Engineering controls attempt to remove the hazard from the workplace or create a barrier between the worker and the hazard. Examples of engineering controls include the installation of alarm systems, panic buttons, hand-held alarms, or noise devices, installation of door locks and increased lighting or use of closed-circuit video monitoring on a 24-hour basis (Haynes, 2013). Other examples include improvements to the layout of the admission area, nurses' stations and rooms. Where appropriate, some hospitals may have metal detectors installed to detect for guns, knives, box cutters, razors, and other weapons.

Effective interventions that have been described in the literature include K–9 security dog teams, metal detectors, and the installation of a security system, that includes metal detectors, cameras, and security personnel (Stirling *et al.,* 2001) and increased lighting (Gerberich *et al.* 2005).

b. Administrative Controls

Administrative controls, sometimes referred to as management policies, include organizational factors and can have a major impact on day-to-day operations in healthcare and social assistance, for both staff and patients/residents. For example, staffing issues, such as mandatory overtime and inadequate staffing levels can lead to increased and unscheduled absences, high turnover, low morale and increased risk of violence for both healthcare and social assistance workers and their patients. Adequate numbers of well-trained staff can help ensure that situations with the potential for violence can be diffused before they escalate into full-blown violent incidents, resulting in fewer injuries. Adequate numbers of staff to address the needs of the patients can result in a higher level of safety and comfort for both patients and staff. Effective training can increase staff confidence and control in preventing, managing and de-escalating these incidents, resulting in a greater sense of safety for both staff and patients.

Employer policies often include security measures to prevent workplace violence, including policies for monitoring and maintaining premises security (*e.g.,* access control systems, video monitoring security systems) and data security (*e.g.,* measures to prevent unauthorized use of employer computer systems and other forms of electronic communication by a patient with a history of violence to obtain personal information about a staff member). Many organizations also have policies that limit or monitor access of nonemployees to the premises. Emergency departments (EDs), because they are typically open 24 hours a day, expose hospitals to the community at large and can pose unique safety and security concerns. If the hospital is located in a community or area with a high crime rate, the crime can spill into the ED.

Zero Tolerance policies are policy statements from employers/management that state that any violence to employees and patients/customers will not be tolerated. In general, zero tolerance policies require and encourage staff to report all assaults or threats to a supervisor or manager. Supervisors and managers keep a log of incidents, and all reports of workplace violence are investigated to help determine what actions to take to prevent future incidents. Some studies in the literature describe and discuss the effectiveness of zero-tolerance policies (Nachreiner *et al.,* 2005; Lipscomb and London, 2015).

Policies that encourage employees to report incidents help ensure that hazards are addressed; however, the current evidence shows that many assaults go unreported (Snyder *et al.,* 2007; Bensley *et al.,* 1997; Gillespie *et al.,* 2014; Kowalenko *et al.,* 2013; Arnetz *et al.,* 2015; Speroni *et al.,* 2014; Pompeii *et al.,* 2015).

Research has shown that injured healthcare and social assistance workers and their employers are reluctant to report violent incidents and resulting injuries out of fear of stigmatizing the patients or residents who are the perpetrators of the violence, particularly when they are mentally ill, developmentally disabled, or cognitively impaired elderly. There is also an attitude among many that violence toward those working with the public, especially with individuals with cognitive impairment, mental illness, or brain injury, is part of the job (Lipscomb and London, 2015; Speroni *et al.,* 2014). Confusion on the part of nurses and other staff about what to report, and what legally constitutes ''assault'' and ''abuse'' as well as the lack of institutional support for reporting incidents can contribute to under-reporting (May and Grubbs, 2002).

c. Personal Protective Equipment

In OSHA's hierarchy of controls, personal protective equipment is the least-preferred type of control because these methods rely on the compliance of all individuals, and often places a burden on the individual worker rather than on the organization as a whole. However, there may be circumstances where the use of personal protective equipment (PPE) is appropriate for preventing workplace violence. For example, the ANA identified the use of gloves, sleeves, and blocking mats as a barrier method to protect staff from bites and scratches when caring for individuals with certain developmental disabilities and where other types of controls are infeasible (Lipscomb and London, 2015).

d. Innovative Strategies

In addition to controls that fall into the traditional OSHA hierarchical approach previously described here, OSHA is also very interested in hearing about strategies and innovations that have been developed from the clinical experience of health professionals, particularly if they have been shown to be effective. The Agency is interested in how existing operations tools, such as electronic infrastructure and work practices, can be modified to support

violence prevention in specific healthcare and social assistance settings. In addition, the Agency seeks information on cross-disciplinary tools and strategies that merge techniques from different disciplines (such as threat assessment, education, and clinical practice) to improve workplace safety and health. Examples of innovative approaches include soliciting information from patients and their families about risk factors and effective solutions through informal surveys or focus groups. One behavioral health facility that hires and employs ''milieu officers,'' typically corrections officers with mental health training whose job is to be visible and accessible on the unit and maintain control over the unit environment as a whole, has reduced violent incidents on some patient units.

New Hampshire Hospital, a state-run behavioral health facility, serves as a teaching hospital through its affiliation with the Geisel School of Medicine at Dartmouth College. This connection allows New Hampshire Hospital to serve as a living laboratory for ongoing research to identify precursors to violence and test new practices. Physicians engage patients as partners in their research, which is part of the hospital's drive for continual improvement. This connection to academic studies also helps to raise awareness of other new research and encourage staff members to adopt the best available evidence-based approaches.

OSHA is interested in hearing from employers and individuals working in healthcare and social assistance about their experiences with hazard prevention and control. Specific questions regarding these topics are at the end of Section V.

4. Safety and Health Training

OSHA's Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers highlight education and training as an essential element of a workplace violence prevention program. Safety and health training helps ensure that all staff members are aware of potential safety hazards and how to protect themselves, their coworkers and patients through established policies and procedures. The content and frequency of training can vary, as well as the staff eligible for training. In general, training covers policies and procedures specific to the facility and perhaps the unit, as well as de-escalation and self-defense techniques. De-escalation of aggressive behavior and managing aggressive behavior when it occurs are very important components of the training (Nonviolent Crisis Intervention Training, 2014).

Training provides opportunities to learn and practice strategies to improve both patient safety and worker safety. The nationwide movement toward reducing the use of restraints (physical and medication) and seclusion in behavioral health—which is mandated in some states—along with the movement toward ''trauma-informed care,'' means that workers are relying more on approaches that minimize physical contact with patients, intervening with verbal de-escalation strategies before an incident turns into a physical assault thereby reducing injuries. Trauma-informed care is a strengths-based approach that is grounded in an understanding of and responsiveness to the impact of trauma, that emphasizes physical, psychological, and emotional safety for both providers and survivors, and that creates opportunities for survivors to rebuild a sense of control and empowerment (SAMHSA). The results can be a ''win-win'' for patient and worker safety (OSHA, 2015b). Training ensures consistent dissemination of information about policies and procedures, as well as an opportunity to practice and develop confidence with newly-learned skills and techniques, such as de-escalation. In particular, when implementing a zero tolerance policy, training staff on what and when to report is essential to changing the expectation that violence will not be tolerated.

Staff training on policies and procedures is usually conducted at orientation and periodically (*e.g.,* annually or semi-annually) afterward. A number of studies show that training can be effective in reducing workplace violence (Swain, 2014; Martin, 1995; Allen, 2013).

Because duties, work locations, and patient interactions vary by job, violence prevention training can be customized to address the needs of different groups of healthcare personnel, particularly: Nurses and other direct caregivers; emergency department (ED) staff; support staff (*e.g.,* dietary, housekeeping, maintenance); security personnel; and supervisors and managers (Greene, 2008). The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) emphasizes that security personnel need specific training on the unique needs of providing security in the healthcare environment, including the psychological components of handling aggressive and abusive behavior, and ways to handle aggression and defuse hostile situations (The Joint Commission, 2009).

OSHA is interested in hearing from employers and individuals working in healthcare and social assistance about their experiences with the various types of training and their effectiveness. Specific questions regarding training are at the end of Section V.

5. Recordkeeping and Program Evaluation

a. Recordkeeping

OSHA's recordkeeping regulations require employers to record certain workplace injuries and illnesses. The OSHA 300 Log can be a valuable source of evaluation metrics data for establishing baseline injury and illness rates and benchmarks for success. Information from the *OSHA 300 Log, 300A Annual Summary, and the 301 Incident Report* can be used to identify tasks and jobs with higher risks of injury or illness, and to monitor trends. Under OSHA's recordkeeping regulation, an employer must record each fatality, injury, and illness that is work-related, a new case, and meets one or more of the general recording criteria in section 1904.7 or the application to specific cases of section 1904.8 through 1904.11. The general recording criteria in section 1904.7 is triggered by an injury or illness that results in death, days away from work, restricted work or transfer to another job, loss of consciousness, or medical treatment beyond first aid. For each such injury, the employer is required to record the worker's name; the date; a brief description of the injury or illness; and, when relevant, the number of days the worker was away from work, assigned to restricted duties, or transferred to another job as a result of the injury or illness. Employers with 10 or fewer employees at all times during the previous calendar year and employers in certain low-hazard industries are partially exempt from routinely keeping OSHA injury and illness records (29 CFR 1904.1, 1904.2). Accurate records of injuries, illnesses, incidents, assaults, hazards, corrective actions, patient histories, and training can help employers evaluate methods of hazard control, identify training needs, and develop solutions for an effective program.

All employers, including those who are partially exempt from keeping records, must report any work-related fatality to OSHA within 8 hours of learning of the incident, and must report all work-related inpatient hospitalizations, amputations, and losses of an eye to OSHA within 24 hours of learning of the incident (29

CFR 1904.39). These events can be reported to OSHA in person, by phone, or by using the reporting application on OSHA's public Web site at *www.osha.gov/recordkeeping. See https://www.osha.gov/recordkeeping2014/.*

Employers do not always record or accurately record workplace injuries and illnesses in general. Specifically, in a 2012 report OSHA found that for calendar years 2007 and 2008, approximately 20 percent of injury and illness cases reconstructed by inspectors during a review of employee records were either not recorded or incorrectly recorded by the employer (OSHA, 2012). BLS is working on improving reporting by conducting additional research on the extent to which cases are undercounted in the SOII and exploring whether computer-assisted coding can improve reporting (BLS, 2014). Further, as discussed above in Section V.A.3.b, there are a number of published studies that show that employees substantially underreport workplace violence cases.

OSHA is interested in hearing from employers and individuals in healthcare and social assistance facilities about their experiences with both recordkeeping to comply with OSHA requirements as well as reporting of incidents at the facility or unit level. Specific questions regarding recordkeeping are at the end of Section V.

b. Program Evaluation

Programs are evaluated to identify deficiencies and opportunities for improvement. Accurate records of injuries and illnesses can help employers gauge the effectiveness of intervention efforts. The evaluation of a comprehensive workplace violence prevention program typically includes, but is not limited to, measuring improvement based on lowering the frequency and severity of workplace violence incidents; keeping up-to-date records of administrative and work practice changes implemented to prevent workplace violence (to evaluate how well they work); surveying workers before and after making job or worksite changes or installing security measures or new systems to evaluate their effectiveness; tracking recommendations through to completion; keeping abreast of new strategies available to prevent and respond to violence as they develop; and establishing an ongoing relationship with local law enforcement and educating them about the nature and challenges of working with potentially violent patients. The quality and effectiveness of training is particularly important to assess.

OSHA is interested in hearing from employers and individuals in healthcare and social assistance facilities about their experiences with program evaluation. Specific questions regarding program evaluation are located in section V.3. below.

B. Questions for Section V

OSHA is interested in hearing from employers and individuals in facilities that provide healthcare and social assistance about their experiences with the various components of workplace violence prevention programs that are currently being implemented by their facilities. Wherever possible, please indicate the title of the person completing the question and the type and employee size of your facility. In particular, the Agency appreciates respondents addressing the following:

1. Questions on the Overall Program, Management Commitment and Employee Participation

Question V.1: Does your facility have a workplace violence prevention program or policy? If so, what are the details of the program or policy? Please describe the requirements of your program, or submit a copy, if feasible. When and how did you implement the program or policy? How many hours did it take to develop the requirements? Did you consult your workers through union representatives?

Question V.2: How is your program or policy communicated to workers? (*e.g.,* Web site, employee meetings, signage, etc.) How are employees involved in the design or implementation of the program or policy?

Question V.3: In your experience, what are the important factors to consider when implementing a workplace violence prevention program or policy?

Question V.4: At what level in your organization was the workplace violence prevention program or policy implemented? Who has responsibility for implementation? What are the qualifications of the person responsible for its implementation?

Question V.5: How well is your program or policy followed? Have you received sufficient support from management? Employees? The union, if there is one?

Question V.6: How did you select the approach to workplace violence prevention outlined in your facility program or policy (*e.g.,* triggered by an incident, following existing guidelines, listening to staff needs, complying with state laws)?

Question V.7: Do you have a safety and health program in place in your facility? If so, what is the relationship between the workplace violence prevention program and the safety and health management system?

Question V.8: Does your facility subscribe to a management philosophy that encompasses quality measures, *e.g.,* lean sigma, high reliability? If so, are metrics for worker safety included?

Question V.9: Does your facility have a safety and health committee? Does your facility also have a workplace violence committee? If so, what is the function of these committees? How are they held accountable? How is progress measured?

Question V.10: Does your facility have a workplace violence prevention committee that is separate from the general safety committee or part of it? If separate, how do the two committees communicate and share information? How many hours do they spend meeting or doing committee work? How many hours of employee time does this require per year?

Question V.11: If the facility does not have a committee, are there reasons for that?

Question V.12: What is the make-up of the committee? How are the committee members selected? What is the highest level of management that participates? Are worker/union representatives included in a committee? Is there a rotation for the committee members?

Question V.13: What does the decision making process look like? Do the committee members play an equal role in the decision making? Is there a meeting agenda? Does the committee keep minutes and records of decisions made?

Question V.14: How are the workplace violence prevention committee's decisions disseminated to the staff and management? Does the committee address employees' safety concerns in a timely manner?

Question V.15: If OSHA were to require management commitment, how should the Agency determine compliance?

Question V.16: If OSHA were to issue a standard that included a requirement for employee participation, how might compliance be determined?

2. Questions on Worksite Analysis and Hazard Identification

Question V.17: Are workplace analysis and hazard identification performed regularly? If so, what is the frequency or triggers for these activities? Are there any assessment tools or overall approaches that you have found

to be successful and would recommend? Please describe the types of successes or problems your facility encountered with reviewing records, administering employee surveys to identify violence-related risk factors, and conducting regular walkthrough assessments.

Q*uestion V.18:* Who is involved in workplace analysis? How are the individuals selected and trained to conduct the workplace analysis and hazard identification? How long does it take to perform the workplace analysis?

Question V.19: What areas of the facility are covered during the routine workplace assessment? Please specify why these areas are included in the assessment and how many of these areas are part of the assessment.

Question V.20: What records do you find most useful for identifying trends and risk factors with regards to workplace violence? How many of these records are collected per year?

Question V.21: What screening tools do you use for the worksite analysis? Are these screening tools designed specifically to meet your facility's needs? Are questionnaires and surveys an effective way to collect information about the potential and existing workplace violence hazards? Why or why not?

Question V.22: Who provides post-assessment feedback? Is it shared with other employees and if so, how is it shared with the other employees?

Question V.23: Does your facility use patient threat assessment? If so, do you use an existing tool or did you develop your own? If you develop your own, what criteria do you use?

Question V.24: Does your facility conduct accident/incident investigations? If so, who conducts them? How are follow-ups conducted and changes implemented?

Question V.25: How much time is required to conduct your patient assessments? What is the occupational background of persons who do these assessments?

Question V.26: If OSHA were to implement a standard with a requirement for hazard identification and worksite analysis, how might compliance be determined?

Question V.27: What do you know or perceive to be risk factors for violence in the facilities you are familiar with?

3. Questions on Hazard Prevention and Controls

Question V.28: Are you aware of any specific controls or interventions that have been found to be effective in reducing workplace violence in an ED environment? How was effectiveness determined? If so, can you provide cost information?

Question V.29: Are you aware of any specific controls or interventions that have been found to be effective in reducing workplace violence in a behavioral health, psychiatric or forensic mental health setting? How was effectiveness determined? If so, can you provide cost information?

Question V.30: Are you aware of any specific controls or interventions that have been found to be effective in reducing workplace violence in a nursing home or long-term care environment? How was effectiveness determined? If so, can you provide cost information?

Question V.31: Are you aware of any specific controls or interventions that have been found to be effective in reducing workplace violence in a hospital environment? How was effectiveness determined? If so, can you provide cost information?

Question V.32: Are you aware of any specific controls or interventions that have been found to be effective in reducing workplace violence in a home health environment? How was effectiveness determined? If so, can you provide cost information?

Question V.33: Are you aware of any specific controls or interventions that have been found to be effective in reducing workplace violence of any other environments where healthcare and/or social assistance workers are employed? How was effectiveness determined? If so, can you provide cost information?

Question V.34: Are you aware of any existing or modified infrastructure and work practices, or cross-disciplinary tools and strategies that have been found to be effective in reducing violence?

Question V.35: Have you made modifications of your facility to reduce risks of workplace violence? If so, what were they and how effective have those modifications been? Please provide cost for each modification made. Please specify the type of impact the modification made and whether the modification resulted in a safer workplace.

Question V.36: Does your facility have controls for workplace violence prevention (security equipment, alarms, or other devices)? If so, what kind of equipment does your facility use to prevent workplace violence? Where is the equipment located? Are there any barriers that prevent using the equipment? What labor requirements or other operating costs does this equipment have (*e.g.,* have you hired security guards to monitor video cameras)?

Question V.37: Who is usually involved in selecting the equipment? If a committee, please list the titles of the committee members. Is new equipment tested before purchase, and if so, by whom? Are there any pieces of equipment purchased that are rarely used? If so, why?

Question V.38: Is there a process for evaluating the effectiveness of controls once they are implemented? What are the evaluation criteria?

Question V.39: What best practices are in use in your facility for workplace violence prevention?

Question V.40: How do you assure that the program is followed and controls are used? What are the ramifications for not following the program or using the equipment? If OSHA were to issue a standard, how might compliance with hazard prevention and control be determined?

Question V.41: Do you have information on changes in work practices or administrative controls (other than engineering controls and devices) that have been shown to reduce or prevent workplace violence either in your facility or elsewhere?

Question V.42: Do you have a zero tolerance policy? If so please share it. Do you think it has been successful in reducing workplace violence incidents? Why or why not?

Question V.43: If you have a policy for reporting workplace violence incidents, what steps have you taken to assure that all incidents are reported? What requirements do you have to ensure that adequate information about the incident is shared with coworkers? Do you think these policies have been effective in improving the reporting and communication about workplace violence incidents? Why or why not?

Question V.44: What factors do you consider in staffing your security department? What are the responsibilities of your security staff?

Question V.45: Have you instituted policies or procedures to identify patients with a history of violence, either before they are admitted or upon admission? If so, what costs are associated with this? How is this information used and conveyed to staff? Whose responsibility is it and what is the process? Has it been effective?

4. Questions on Safety and Health Training

Question V.46: What kind of training on workplace violence prevention is provided to the healthcare and/or social assistance workers at your facility? If

this is copyrighted/branded training, please provide the name.

Question V.47: What is the scope and format of the training, and how often is workplace violence prevention training conducted?

Question V.48: What occupations (*e.g.,* registered nurses, nursing assistants, etc.) attend the training sessions? Are the staff members required to attend the training sessions or is attendance voluntary? Are staff paid for the time they spend in training? Who administers the training sessions? Are they in-house training staff or a contractor? How is the effectiveness of the training measured? What is the duration of the training sessions or cost of the contractor?

Question V.49: Do all employees have education or training on hazard recognition and controls?

Question: V.50: Are contract and per diem employees trained?

Question V.51: Are patients educated on the workplace violence prevention program and, if so, how?

Question V.52: Does training cover workers' rights (including non-retaliation) and incident reporting procedures?

Question V.54: If OSHA were to require workplace violence prevention training, how might compliance be assessed?

5. Questions on Recordkeeping and Program Evaluation

Question V.55: Does your facility have an injury and illness recordkeeping policy and/or standard operating procedures? Please describe how it works. How are records maintained; online, paper, in person?

Question V.56: Who is responsible for injury and illness recordkeeping in your facility?

Question V.57: Does your facility use a workers' compensation form, the OSHA 301 or another form to collect detailed information on injury and illness cases?

Question V.58: Where are the OSHA 300 log(s) kept at your facility? Are they kept on each unit, each floor, or are they centrally located for the entire facility?

Question V.59: Would the OSHA 300 Log alone serve as a valuable or sufficient tool for evaluating workplace violence prevention programs? Why or why not?

Question V.60: Are you aware of any issues with reporting (either underreporting or overreporting) of OSHA recordables and/or ''accidents'' or other incidents related to workplace violence in your facility and if so, what types of issues? If you have addressed them, how did you address them?

Question V.61: Do you regularly evaluate your program? If so, how often? Is there an additional assessment after a violent event or a near miss? If so, how do you measure the success of your program? How many hours does the evaluation take to complete?

Question V.62: Who is involved in a program evaluation at your facility? Is this the same committee that conducted the workplace analysis and hazard identification?

Question V.63: If you have or are conducting an evaluation of the effectiveness of your workplace violence prevention program, have you been able to demonstrate improved tracking of workplace violence incidents and/or a reduction in the frequency or severity of violent incidents?

Question V.64: What are the most effective parts of your program? What elements of your program need improvement and why?

Question V.65: When conducting program evaluations, do you use the same tools and metrics you used for the initial worksite assessment? If not, please explain.

Question V.66: If OSHA were to develop a standard to prevent workplace violence and included a requirement for program or policy evaluation, how might compliance be determined?

Question V.67: Could you provide information characterizing the nature and extent of the difficulties in implementing your facility's program or policy?

Question V.68: What actions are taken based on the results of the program evaluation at your facility?

VI. Costs, Economic Impacts, and Benefits

As part of the Agency's consideration of a possible workplace violence standard, OSHA is interested in the costs, economic impacts, and benefits of related practices. OSHA is also interested in the benefits of such practices in terms of reduced injuries, deaths, and compromised operations (*i.e.,* emotional distress, staffing turnover, and unexpected reallocation of resources).

Workplace violence exacts a high cost today. It harms workers often both physically and emotionally, and employers also bear several costs. A single serious injury can lead to workers' compensation losses of thousands of dollars, along with thousands of dollars in additional costs for overtime, temporary staffing, or recruiting and training a replacement. Even if a worker does not have to miss work, violence can still lead to ''hidden costs'' such as higher turnover and deterioration of productivity and morale. In the study of Washington state's workers' compensation data (1997–2007), the average cost claim per time-lost was $32,963, with an annual average of at least 2,247 claims related to workplace violence in Washington State for the period from 1997–2007. Similar costs were cited by McGovern *et al.* (2000) who found costs per case for assaults was $31,643 for registered nurse and $17,585 for licensed practical nurses. These costs included medical expenses, lost wages, legal fees insurance administrative costs, lost fringe benefits, and household production costs.

In addition to the out-of-pocket costs by the employer and employee, healthcare workers who experience workplace violence have reported short term and long term emotional effects which can negatively impact productivity. It was found by Gates *et al.* (2003; 2006) that nursing assistants employed in long term care, who had been assaulted suffered a range of occupational stressors including job dissatisfaction, decreased safety, and fear of future assaults. Caldwell (1992) and Gerberich *et al.* (2004) found emergency department (ED) workers to have post-traumatic stress disorder or symptom of the disorder at rates between 12 percent to 20 percent; the 12-month prevalence rate for the general U.S. adult population is about 3.5 percent (*http://www.nimh.nih.gov/health/statistics/prevalence/post-traumatic-stress-disorder-among-adults.shtml*). The impact of PTSD caused by workplace violence on productivity was studied by Gates, Gillespie and Succop (2011), where they found those who suffered from PTSD symptoms or experienced emotional distress reported difficulty thinking, withdrawal from patients, absenteeism, and higher job turnover. The results also found that, although emergency department nurses with PTSD symptoms continued to work, they had trouble remaining cognitively focused, and had ''difficulty managing higher level work demands that required attention to detail or communication skills.''

OSHA requests any workers' compensation data related to workplace violence. Any other information on your facility's experience would also be appreciated.

Several studies have evaluated the effectiveness of various engineering and administrative workplace violence controls in a variety of settings (*e.g.,* hospitals, nursing homes). The implementation of a comprehensive

workplace violence prevention program that includes administrative and engineering controls has been shown to lead to lower injury rates and workers' compensation costs (Foley and Rauser, 2012, updated data provided to OSHA by the authors in 2015).

A. Questions for Costs, Economic Impacts, and Benefits

The following questions are intended to solicit information on the topics covered in this section. Wherever possible, please indicate the title of the person providing the information and the type and number of employees at your healthcare and/or social assistance facility.

Question VI.1: Are there additional data (other than workers' compensation data) from published or unpublished sources that describe or inform about the incidence or prevalence of workplace violence in healthcare occupations or settings?

Question VI.2: As the Agency considers possible actions to address the prevention and control of workplace violence, what are the potential economic impacts associated with the promulgation of a standard specific to the risk of workplace violence? Describe these impacts in terms of benefits from the reduction of incidents; effects on revenue and profit; and any other relevant impact measure.

Question VI.3: If you have implemented a workplace violence prevention program or policy, what was the cost of implementing the program or policy, in terms of both time and expenditures for supplies and equipment? Please describe in detail the resource requirements and associated costs expended to initiate the program(s) and to conduct the program(s) annually. If you have any other estimates of the costs of preventing or mitigating workplace violence, please provide them. It would be helpful to OSHA to learn both overall totals and specific components of the program (*e.g.,* cost of equipment, equipment installation, equipment maintenance, training programs, staff time, facility redesign).

Question VI.4: What are the ongoing operating and maintenance costs for the program?

Question VI.5: Has your program reduced incidents of workplace violence and by how much? Can you identify which elements of your program most reduced incidents? Which elements did not seem effective?

Question VI.6: Has your program reduced costs for your facility (*e.g.,* reduced insurance premiums, workers' compensation costs, fewer lost workdays)? Please quantify these reductions, if applicable.

Question VI.7: Has your program reduced indirect costs for your facility (*e.g.,* reductions in absenteeism and worker turnover; increases in reported productivity, satisfaction, and level of safety in the workplace)?

Question VI.8: If you are in a state with standards requiring programs and/or policies to reduce workplace violence, how did implementing the program and/or policy affect the facility's budget and finances?

Question VI.9: What changes, if any, in market conditions would reasonably be expected to result from issuing a standard on workplace violence prevention? Describe any changes in market structure or concentration, and any effects on services, that would reasonably be expected from issuing such a standard.

B. Impacts on Small Entities

As part of the Agency's consideration of a workplace violence prevention standard, OSHA is concerned whether its actions will have a significant economic impact on a substantial number of small businesses. Injury and illness incident rates are known to vary by establishment size in the healthcare industry, where establishments between 50 and 999 employees had a rate of 5.4 per 10,000 full time workers, while establishments under 50 employees had a rate of 2.8 and lower in 2014 (BLS Table Q1, October 2015).

If the Agency pursues development of a standard that would have such impacts on small businesses, OSHA is required to develop a regulatory flexibility analysis and convene a Small Business Advocacy Review (SBAR) under the Small Business Regulatory Enforcement Fairness Act (SBREFA) Panel prior to publishing a proposal. Regardless of the significance of the impacts, OSHA seeks ways of minimizing the burdens on small businesses consistent with OSHA's statutory and regulatory requirements and objectives (Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*).

C. Questions for Impacts on Small Entities

Question VI.10: How many, and what type of small firms, or other small entities, have a workplace violence prevention training, or a program, and what percentage of their industry (NAICS code) do these entities comprise? Please specify the types of workplace violence risks you face.

Question VI.11: How, and to what extent, would small entities in your industry be affected by a potential OSHA standard to prevent workplace violence? Do special circumstances exist that make preventing workplace violence more difficult or more costly for small entities than for large entities? Describe these circumstances.

Question VI.12: How many, and in what type of small healthcare entities, is workplace violence a threat, and what percentage of their industry (NAICS code 622) do these entities comprise?

Question VI.13: How, and to what extent, would small entities in your industry be affected by an OSHA standard regulating workplace violence? Are there conditions that make controlling workplace violence more difficult for small entities than for large entities? Describe these circumstances.

Question VI.14: Are there alternative approaches OSHA could use to mitigate possible impacts on small entities?

Question VI.15: For very small entities, what types of workplace violence threats are faced by workers? Does your experience with workplace violence reflect the lower rates reported by BLS?

Question VI.16: For very small entities, what are the unique challenges establishments face in addressing workplace violence, including very small non-profit healthcare facilities and at small jurisdictions?

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Authority and Signature: Dr. David Michaels, Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice pursuant to 29 U.S.C. 653, 655, and 657, Secretary's Order 1–2012 (77 FR 3912; Jan. 25, 2012), and 29 CFR part 1911.

Signed at Washington, DC, on December 1, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2016–29197 Filed 12–6–16; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 175

RIN 0790–AJ54

[Docket ID: DOD–2016–OS–0108]

Indemnification or Defense, or Providing Notice to the Department of Defense, Relating to a Third-Party Environmental Claim

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The DoD proposes to identify the proper address and notification method for an entity making a request for indemnification or defense, or providing notice to DoD, of a third-party claim under section 330 of the National Defense Authorization Act for Fiscal Year 1993, as amended (hereinafter ''section 330''), or under section 1502(e) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, (hereinafter ''section 1502(e)''). This rule also identifies the documentation required to demonstrate proof of any claim, loss, or damage for indemnification or defense or for providing notice to DoD of a third-party claim. This rule also provides the mailing address for such requests for indemnification or defense or notice to DoD of a third-party claim to be filed with DoD, Office of General Counsel, Deputy General Counsel for Environment, Energy, and Installations (DoDGC(EE&I)). This will allow for timely review and greater efficiency in screening requests for indemnification or defense by providing clarity to requesters.

DATES: Written comments on this proposed rule will be accepted on or before February 6, 2017.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management

Officer, Directorate of Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN 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: Mr. Philip Sheuerman, 703–692–2287.

SUPPLEMENTARY INFORMATION:

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I. Legal Authority

This part is proposed under 10 U.S.C. 113, 5 U.S.C. 301, section 330 of the National Defense Authorization Act for Fiscal Year 1993, Public Law 102–484, October 23, 1992, 106 Stat. 2371, as amended, and section 1502(e) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law 106–398, October 30, 2000, 1014 Stat. 1654A–350, as amended.

II. Background

Sections 330 and 1502(e) provide that, subject to certain exceptions set forth in the statutes, the Secretary of Defense shall hold harmless, defend, and indemnify in full certain persons and entities that acquire ownership or control of, in the case of section 330, any military installation closed pursuant to a base closure law or, in the case of section 1502(e), certain portions of the former Naval Ammunition Support Detachment on the island of Vieques, Puerto Rico (hereinafter ''Detachment''), from and against any suit, claim, demand or action, liability, judgment, cost or other fee arising out of any claim for personal injury or property damage (including death, illness, or loss of or damage to property or economic loss) that results from, or is in any manner predicated upon, the release or threatened release of any hazardous substance, pollutant or contaminant, or petroleum or petroleum derivative [1] as a result of DoD activities at any military installation (or portion thereof) that is closed pursuant to a base closure law or the Detachment. (Coverage of pollutants and contaminants was added to section 330 by an amendment contained in the National Defense Authorization Act for Fiscal Year 1994, Public Law 103–160, 1002.) It also provides that DoD has certain rights in defending third-party claims.

The authority to adjudicate requests for indemnification and process requests for defense under sections 330 or 1502(e) has been delegated from the Secretary of Defense to the DoD General Counsel and re-delegated by the General Counsel to DoDGC(EE&I). Requests for indemnification or defense or notice to DoD of a third-party claim must be sent to DoDGC(EE&I) to be considered.

The DoD recognizes that some real property transfer documents, such as deeds and agreements, entered into in past years provide for notification under sections 330 or 1502(e) being made to, *e.g.,* the local BRAC program office. Until the promulgation of this rule in its final form, DoD has and will continue to honor such notifications made in conformance with those transfer documents. Effective 180 days after promulgation of this rule, while a requester may continue to provide notification in accordance with such transfer documents, a requester must also comply with the notice requirements of this rule in order to comply with the requirements of sections 330 or 1502(e), particularly with regard to when the statutes of limitation in sections 330(b)(1) and 1502(e)(2)(A) begin to run. Nothing in this rule should be construed as requiring amendment of any such transfer documents.

The United States Federal Circuit has interpreted the definition of a ''claim for personal injury or property damages'' under section 330 to include, under certain circumstances, notice from an enforcement agency to conduct a cleanup. *Indian Harbor Insurance Co.* v. *United States,* 704 F.3d 949 (Fed. Cir. 2013). Because such notices may constitute a claim under section 330, a requester should carefully evaluate whether failing to provide notice to the Secretary would prevent the Secretary from settling or defending against a claim.

The timely and proper filing of a request for indemnification or defense enables DoDGC(EE&I) to perform its adjudication function for requests, maintain oversight of the implementation of sections 330 and 1502(e), and secure the rights of requesters under sections 330 and 1502(e). Proper notice to DoD of a claim from a third-party is also essential to allow DoD to exercise its right to defend against such a claim pursuant to sections 330(c) or 1502(e).

Under sections 330(c)(2) and 1502(e)(3)(B), the requester must allow DoD to defend the claim in order to be afforded indemnification for that claim. This regulation makes clear that failure to notify DoD immediately of receipt of any claim, or of a release that may lead to a claim, could prevent DoD from settling or defending that claim, and on that basis, DoD may deny indemnification. Failure to provide necessary documents and access will also prevent DoD from exercising its right to settle and defend the claim and, on that basis, DoD may deny indemnification.

In the context of a claim from an enforcement agency or third party seeking to require a cleanup or response action, failure to notify DoD may prevent DoD from exercising its right to defend against the claim. If the requester undertakes a cleanup or response action itself prior to providing immediate notice to DoD, the requestor's actions may interfere with DoD's ability to defend against a claim, which might result in denial of indemnification.

This proposed rule does not affect claims that are made pursuant to other authorities such as under a real property covenant contained in a deed in accordance with section 120(h) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA).

III. Summary of Proposed Rule

This proposal identifies the required process for submitting documentation necessary to support a request for indemnification or defense or to provide notice to DoD of a third-party claim under sections 330 or 1502(e). For a notice to DoD of a third-party claim, DoDGC(EE&I) must receive the specified paperwork at the specified address no less than 30 days after a requester

[1] Section 1502(e) does not apply to petroleum or petroleum derivatives.

receives a third-party claim or before any action is taken, or an agreement is entered into, related to a hazardous substance or a pollutant or contaminant, or petroleum or petroleum derivative covered by section 330 or a hazardous substance or a pollutant or contaminant covered by section 1502(e).

IV. Section-by-Section Analysis

A. Purpose

To ensure the proper implementation of sections 330 and 1502(e), requesters and DoD must communicate effectively and in a timely manner. This proposal will provide the necessary information for that interaction to take place.

B. Applicability

This proposal applies to the DoD General Counsel's Office, to the Military Departments, and to any person or entity making a request for indemnification or defense, or providing notice to DoD, of a third-party claim pursuant to sections 330 or 1502(e).

C. Definitions

This proposal defines the terms ''commercial delivery service'', ''Deputy General Counsel'', ''received'', ''request'', ''requester'', ''section 330'', ''section 1502(e)'', and ''third-party claim''.

D. Responsibilities

This proposal advises that the responsibilities of the Secretary of Defense under sections 330 and 1502(e) have been delegated to the General Counsel of the DoD who has, in turn, re-delegated certain of those responsibilities, particularly with regard to adjudication of requests for indemnification, to DoDGC(EE&I). DoDGC(EE&I) exercises this responsibility through close communication with the military department that has property disposal responsibility for the closed installation subject of the request for indemnification or defense. Such communication includes obtaining review by, and the recommendations of, the military department on the merits of the request for indemnification or defense. Likewise, DoDGC(EE&I) communicates any notice of a third-party claim to the military department and works closely with the military department in determining what action, if any, the DoD will take in response to the notice. The proposal also contains responsibilities of requesters, delineated in the body of the rule.

E. Requests for Indemnification or Defense

This proposal explains the process to be used, timelines that apply, and documentation that must be received by DoDGC(EE&I) for a request for indemnification or defense. The mailing address and required method of delivery are specified. The proposal also requires a requester to provide DoD with a right of entry at reasonable times for purposes of inspecting the property and obtaining samples. The proposal also provides for reconsideration of a DoD determination.

F. Third-Party Claims

This proposal explains the process to be used, timelines that apply, and documentation that must be received by DoDGC(EE&I) relating to a notice of a third-party claim. The mailing address and required method of delivery are specified. The proposal also requires a requester to provide DoD with a right of entry at reasonable times for purposes of inspecting the property and obtaining samples. The section specifies that a requester must notify DoD within 30 days of receiving the third-party claim or 30 days before taking an action in order to allow DoD to determine what action to take with regard to the claim.

V. Summary of Challenges

Informing all affected persons and entities about this rule will require communication with relevant non-governmental organizations.

VI. Discussion of Other Major Alternatives

A. Status Quo

The current process is unclear, inefficient, and time-consuming, causes delay, and may be ineffective. This lack of clarity contributes to concern that indemnification is not being addressed adequately and creates the potential for impairment of DoD's ability to present an effective defense of claims under sections 330 or 1502(e). The DoD is committed to sound environmental stewardship in all of its activities while meeting the goal of encouraging the development of land for productive use.

VII. Costs and Benefits

Cost Analysis

Based on the relatively small number of claims per year, compliance costs under this regulation are expected to be minimal. In fact, this regulation will reduce compliance costs because it will streamline and clarify the process for the submission of information which would have to be submitted in any case in order to obtain a determination regarding indemnification or defense or provide notice to DoD of a third-party claim under sections 330 or 1502(e).

Benefits Analysis

This proposal will clarify the process for requesters of indemnification or defense and promote efficient protection of the environment by enhancing communication between requesters and DoD. This enhanced and simplified communication process will result in fewer burdens for both requesters and DoD in the form of avoiding unnecessary, inappropriate, or duplicative paperwork. This proposal does not require any greater disclosure of information from a requester than sections 330 or 1502(e) already require. Enhancing DoDGC(EE&I)'s ability to adjudicate requests for indemnification or respond to requests for defense under sections 330 or 1502(e) will reduce the burden of information requests upon those entities requesting indemnification or defense, or providing notice to DoD, of a third-party claim under sections 330 or 1502(e). This proposal will promote protection of requesters' rights by reducing the possibility of a request for indemnification or defense being acted upon by the wrong agency or a statute of limitations running due to failure to provide timely notification to the proper agency.

VIII. Administrative Requirements

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

Under E.O. 12866 and E.O. 13563, DoD must determine whether this regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and to the requirements of this E.O., which include assessing the costs and benefits anticipated as a result of the proposed regulatory action. E.O. 12866 defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the

President's priorities, or the principles set forth in E.O. 12866.

This proposed rule will not have an adverse effect on the economy or cost the economy $100 million or more per year. Requests for indemnification are small in number and do not approach anywhere near $100 million per year, individually or collectively. c Although not economically significant, this rule has been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by OMB under the requirements of these Executive Orders.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601, *et seq.,* requires Federal agencies to consider ''small entities'' throughout the regulatory process. Section 603 of the Regulatory Flexibility Act requires an initial screening analysis performance to determine whether small entities will be adversely affected by the regulation. If affected small entities are identified, regulatory alternatives must be considered to mitigate the potential impacts. Small entities as described in the Regulatory Flexibility Act are only those ''business, organizations and governmental jurisdictions subject to regulation.'' It has been certified that this proposed rule will not add to the current burden for small entities to report their activities based on a request for indemnification or defense under sections 330 or 1502(e). This proposal will benefit small entities by streamlining communication to reduce the cost of making a request for indemnification or defense, or providing notice to DoD, of a third-party claim.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. 3501, authorizes the Director of OMB to review certain information collection requests by Federal agencies. The recordkeeping and reporting requirements of this proposed rule do not constitute a ''collection of information'' as defined in 44 U.S.C. 3502(3), the Paperwork Reduction Act of 1995.

D. Environmental Justice

Under E.O. 12898 (59 FR 7629 (February 11, 1994)), Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, Federal agencies are required to identify and address disproportionately high and adverse human health and environmental effects of Federal programs, policies, and activities on minority and low-income populations. Given the application of this proposed rule throughout the entire United States, DoD is soliciting comment and input from all public entities and government agencies, including members of the environmental justice community and members of the regulated community.

Sections 330 and 1502(e) are intended to reduce specified risks from development of former military land by aiding and legally protecting the entities that take title to land on closed military installations for development purposes. Because this rule will equally affect reporting associated with the development of land on a national basis, a disparate impact on minority and low-income population areas is not expected.

E. Unfunded Mandates

Title II of the Unfunded Mandates Report Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Indian tribal governments and the private sector. Under Section 202 of the UMRA, DoD generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Indian tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

The DoD has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Indian tribal governments, in the aggregate, or the private sector in any one year. Thus, this proposed rule is not subject to the requirements of Section 202 of the UMRA.

F. Executive Order 13132, ''Federalism''

It has been determined that this rule does not have federalism implications. This rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 175

Indemnification, Claim.

■ Accordingly, 32 CFR part 175 is proposed to be added to read as follows:

PART 175—INDEMNIFICATION OR DEFENSE, OR PROVIDING NOTICE TO THE DEPARTMENT OF DEFENSE, RELATING TO A THIRD-PARTY ENVIRONMENTAL CLAIM

Sec.

175.1 Purpose.
175.2 Applicability.
175.3 Definitions.
175.4 Responsibilities.
175.5 Notice to DoD relating to a third-party claim.
175.6 Filing a request for indemnification or defense.

Authority: 10 U.S.C. 113, 5 U.S.C. 301, section 330 of the National Defense Authorization Act for Fiscal Year 1993, Public Law 102–484, October 23, 1992, 106 Stat. 2371, as amended, and section 1502(e) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law 106–398, October 30, 2000, 1014 Stat. 1654A–350, as amended.

§ 175.1 Purpose.

This part describes the process for filing a request for indemnification or defense, or providing proper notice to DoD, of a third-party claim pursuant to section 330 of the National Defense Authorization Act for Fiscal Year 1993, Public Law 102–484, October 23, 1992, 106 Stat. 2371, as amended (hereafter ''section 330''), or section 1502(e) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law 106–398, October 30, 2000, 1014 Stat. 1654A–350, as amended (hereafter ''section 1502(e)''). This process identifies the minimum information that a request for indemnification or defense or notice to DoD of a third-party claim for indemnification must include, where that information must be sent, how to make such a request or provide such a notice, the time limits that apply to such a request or notice, and other requirements.

§ 175.2 Applicability.

(a) This part applies to—

(1) The Office of the General Counsel of the Department of Defense and the Military Departments.

(2) Any person or entity making a request for indemnification or defense, or providing notice to DoD, of a third-party claim pursuant to section 330 or section 1502(e).

(b) In the case of a property that is subject to an earlier agreement containing different notification requirements, the requirement for notice to the Deputy General Counsel in sections 175.5 and 175.6 are in addition to those notification requirements.

§ 175.3 Definitions.

(a) *Commercial delivery service.* Federal Express or United Parcel Service, or other similar service that provides for delivery of packages directly from the sender to the recipient for a fee, but excluding the United States Postal Service (USPS).

(b) *Deputy General Counsel.* The Deputy General Counsel (Environment, Energy, and Installations), Department of Defense (DoDGC(EE&I)).

(c) *Received.* Actual physical receipt by the intended recipient.

(d) *Request.* Any request for indemnification or defense made to the Department of Defense (DoD) by a requester pursuant to section 330 or section 1502(e).

(e) *Requester.* A person or entity making a request pursuant to section 330 or section 1502(e). When the requester is acting by way of subrogation, the requester is subject to the same requirements and limitations as though it were the subrogee.

(f) *Section 330.* Section 330 of the National Defense Authorization Act for Fiscal Year 1993, Pub. L. 102–484, October 23, 1992, 106 Stat. 2371, as amended.

(g) *Section 1502(e).* Section 1502(e) of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Public Law 106–398, October 30, 2000, 114 Stat. 1654A–350. (This provision applies only to certain portions of the former Naval Ammunition Support Detachment on the island of Vieques, Puerto Rico.)

(h) *Third-party claim.* A claim from a person or entity (other than the requester) to a requester resulting from a suit, claim, demand or action, liability, judgment, cost or other fee, demanding, seeking, or otherwise requiring that the requester pay an amount, take an action, or incur a liability for alleged personal injury or property damage and such payment, action, or liability is eligible for indemnification or defense pursuant to section 330 or section 1502(e). A third-party claim may consist of a notice, letter, order, compliance advisory, compliance agreement, or similar direction from a governmental regulatory authority exercising its authority to regulate the release or threatened release of any hazardous substance, pollutant or contaminant, or petroleum or petroleum derivative if the notice, letter, order, compliance advisory, compliance agreement, or similar notification imposes, directs, or demands requirements for environmental actions or asserts damages related thereto that is eligible for indemnification or defense pursuant to section 330 or section 1502(e).

§ 175.4 Responsibilities.

(a) The General Counsel of the Department of Defense has been delegated the authorities and responsibilities of the Secretary of Defense under section 330 or section 1502(e), with certain limitations as to re-delegation.

(b) The General Counsel has re-delegated the authority and responsibility to adjudicate requests for indemnification or defense and to process notices to DoD of a third-party claim under section 330 and section 1502(e) to the Deputy General Counsel, Environment, Energy, and Installations, of the Department of Defense or, when the position of Deputy General Counsel is vacant, the acting Deputy General Counsel. The authority to acknowledge receipt of a request has been delegated to an Associate General Counsel under the Deputy General Counsel, Environment, Energy, and Installations.

§ 175.5 Notice to DoD relating to a third-party claim.

(a) *Where to file a notice to DoD of a third-party claim.* Notice to DoD of receipt of a third-party claim, or intent to enter into, agree to, settle, or solicit such a claim, must be received by the Deputy General Counsel at the following address: Deputy General Counsel, Environment, Energy, and Installations, 1600 Defense Pentagon, Room 3B747, Washington, DC 20301–1600. Delivering or otherwise filing a notice of a third-party claim with any other office or location will not constitute proper notice for purposes of this part. Requesters should be aware that all delivery services, and particularly that of the USPS, to the Pentagon can be significantly delayed for security purposes and they should plan accordingly in order to meet any required filing deadlines under this part; use of a commercial delivery service may reduce the delay.

(b) *Individual requests.* A notice to DoD of a third-party claim must be filed separately for each person or entity that is filing the notice. Notices may not be filed jointly for a group, a class, or for multiple persons or entities.

(c) *Means of filing a notice of a third-party claim.* A notice of a third-party claim must be submitted in writing by mail through the USPS or by a commercial delivery service. While the Deputy General Counsel will affirmatively acknowledge receipt of a notice of a third-party claim, it is recommended that a requester, whether using the USPS or a commercial delivery service, mail its notice by registered or certified mail, return receipt requested, or equivalent proof of delivery.

(d) *Information to be included in a notice to DoD of a third-party claim.* A notice to DoD of a third-party claim must include, at a minimum, the following information:

(1) A complete copy of the third-party claim, or, if not presented in writing, a complete summary of the claim, with the names of officers, employees, or agents with knowledge of any information that may be relevant to the claim or any potential defenses. The third-party claim may consist of a summons and complaint or, in the case of a third-party claim from a governmental regulatory authority, a notice, letter, order, compliance advisory, compliance agreement, or similar notification.

(2) A complete copy of all pertinent records, including any deed, sales agreement, bill of sale, lease, license, easement, right-of-way, or transfer document for the facility for which the third-party claim is made.

(3) If the requester is not the first transferee from DoD, a complete copy of all intervening deeds, sales agreements, bills of sale, leases, licenses, easements, rights-of-way, or other transfer documents between the original transfer from DoD and the transfer to the current owner. If the requester is a lender who has made a loan to a person or entity who owns, controls, or leases the facility for which the request for indemnification is made that is secured by said facility, complete copies of all promissory notes, mortgages, deeds of trust, assignments, or other documents evidencing such a loan by the requester.

(4) A complete copy of any insurance policies related to such facility.

(5) If the notice to DoD of a third-party claim is being made by a representative, agent, or attorney in fact or at law, proof of authority to make the notice on behalf of the requester.

(6) Evidence or proof of any claim, loss, or damage alleged to be suffered by the third-party claimant which the requester asserts is covered by section 330 or by section 1502(e).

(7) In the case where a requester intends to enter into, agree to, settle, or solicit a third-party claim, a description or copy of the proposed claim, settlement, or solicitation, as the case may be.

(8) To the extent that any environmental response action has been taken, the documentation supporting such response action and its costs included in the request for indemnification.

(9) To the extent that any environmental response action has been taken, a statement as to whether the remedial action is consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (Part 300 of title 42, Code of Federal Regulations) or other applicable regulatory requirements.

(10) A complete copy of any claims made by the requester to any other entity related to the conditions on the property which are the subject of the claim, and any responses or defenses thereto or made to any third-party claims, including correspondence, litigation filings, consultant reports, and other information supporting a claim or defense.

(e) *Entry, inspection, and samples.* The requester must provide DoD a right of entry at reasonable times to any facility, establishment, place, or property under the requester's control which is the subject of or associated with the requester's notice of third-party claim and must allow DoD to inspect or obtain samples from that facility, establishment, place, or property.

(f) *Additional information.* The Deputy General Counsel will advise a requester in writing of any additional information that must be provided to defend against a claim. Failure to provide the additional information in a timely manner may result in denial of a request for indemnification or defense for lack of information to adjudicate the claim.

(g) *When to file a notice to DoD of a third-party claim.*

(1) A requester must, within 30 days of receiving a third-party claim, file with DoD a notice of such claim in accordance with this part. Failure to timely file such a notice, if it in any way compromises the ability of DoD to defend against such a claim pursuant to section 330(c) or section 1502(e)(3), will result in denial of any subsequent request for indemnification or defense resulting from such a claim. Requesters who take action in compliance with any such third-party claim, or any part of such claim, without first providing DoD with a notice of such claim in accordance with this section do so at their own risk.

(2) A requester must, at least 30 days prior to the earlier of entering into, agreeing to, settling, or soliciting a third-party claim, file a notice to DoD of such intent in accordance with this part. Failure to file such a notice will compromise the ability of DoD to defend against such a claim pursuant to section 330(c) or section 1502(e)(3) and will result in denial of any subsequent request for indemnification or defense resulting from such a claim.

(h) *No implication from DoD action.* Any actions taken by DoD related to defending a claim do not constitute a decision by DoD that the requester is entitled to indemnification or defense.

(i) *Notice also constituting a request for indemnification or defense.* Notice of receipt of a third-party claim may constitute a request for indemnification or defense if that notice complies with all applicable requirements for a request for indemnification or defense.

§ 175.6 Filing a request for indemnification or defense.

(a) *Where to file a request for indemnification or defense.* In order to notify DoD in accordance with section 330(b)(1) or section 1502(e)(2)(A), a request for indemnification or defense pursuant to section 330 or section 1502(e) must be received by the Deputy General Counsel at the following address: Deputy General Counsel, Environment, Energy, and Installations, 1600 Defense Pentagon, Room 3B747, Washington, DC 20301–1600. Delivering or otherwise filing a request for indemnification or defense with any other office or location will not constitute proper notice of a request for purposes of section 330(b)(1) or section 1502(e)(2)(A). Requesters should be aware that all delivery services, and particularly that of the USPS, to the Pentagon can be significantly delayed for security purposes and they should plan accordingly in order to meet any required filing deadlines under this part; use of a commercial delivery service may reduce the delay.

(b) *When to file a request for indemnification or defense.* A request for indemnification must be received by the Deputy General Counsel within two years after the claim giving rise to the request accrues. A request for defense must be received by the Deputy General Counsel in sufficient time to allow the United States to provide the requested defense.

(c) *Means of filing a request for indemnification or defense.* A request for indemnification or defense must be submitted in writing by mail through the USPS or by a commercial delivery service. While the Deputy General Counsel will affirmatively acknowledge receipt of a request for indemnification or defense, it is recommended that a requester, whether using the USPS or a commercial delivery service, mail its request by registered or certified mail, return receipt requested, or equivalent proof of delivery.

(d) *Individual requests.* A request for indemnification or defense must be filed separately for each person or entity that is making the request. Requests may not be filed jointly for a group, a class, or for multiple persons or entities.

(e) *Information to be included in a request for indemnification or defense.* A request for indemnification or defense must include, at a minimum, the following information:

(1) A complete copy of the third-party claim, or, if not presented in writing, a complete summary of the claim, with the names of officers, employees, or agents with knowledge of any information that may be relevant to the claim or any potential defenses.

(2) A complete copy of all pertinent records, including any deed, sales agreement, bill of sale, lease, license, easement, right-of-way, or transfer document for the facility for which the request for indemnification or defense is made.

(3) If the requester is not the first transferee from DoD, a complete copy of all intervening deeds, sales agreements, bills of sale, leases, licenses, easements, rights-of-way, or other transfer documents between the original transfer from DoD and the transfer to the current owner. If the requester is a lender who has made a loan to a person or entity who owns, controls, or leases the facility for which the request for indemnification is made that is secured by said facility, complete copies of all promissory notes, mortgages, deeds of trust, assignments, or other documents evidencing such a loan by the requester.

(4) A complete copy of any insurance policies related to such facility.

(5) If the request for indemnification or defense is being made by a representative, agent, or attorney in fact or at law, proof of authority to make the request on behalf of the requester.

(6) Evidence or proof of any claim, loss, or damage covered by section 330 or by section 1502(e).

(7) In the case of a request for defense, a copy of the documents, such as a summons and complaint, or enforcement order, representing the matter against which the United States is being asked to defend.

(8) To the extent that any environmental response action has been taken, the documentation supporting such response action and its costs included in the request for indemnification.

(9) To the extent that any environmental response action has been taken, a statement as to whether the remedial action is consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (Part 300 of title 42, Code of Federal Regulations) or other applicable regulatory requirements.

(10) A complete copy of any claims made by the requester to any other entity related to the conditions on the property which are the subject of the claim, and any responses or defenses thereto or made to any third-party claims, including correspondence, litigation filings, consultant reports, and

other information supporting a claim or defense.

(f) *Entry, inspection, and samples.* The requester must provide DoD a right of entry at reasonable times to any facility, establishment, place, or property under the requester's control which is the subject of or associated with the requester's request for indemnification or defense and must allow DoD to inspect or obtain samples from that facility, establishment, place, or property.

(g) *Additional information.* The Deputy General Counsel will advise a requester in writing of any additional information that must be provided to adjudicate the request for indemnification or defense. Failure to provide the additional information in a timely manner may result in denial of the request for indemnification or defense.

(h) *Adjudication.* The Deputy General Counsel will adjudicate a request for indemnification or defense and provide the requester with DoD's determination of the validity of the request. Such determination will be in writing and sent to the requester by certified or registered mail.

(i) *Reconsideration.* Any such determination will provide that the requester may ask for reconsideration of the determination. Such reconsideration shall be limited to an assertion by the requester of substantial new evidence or errors in calculation. The requester may seek such reconsideration by filing a request to that effect within 30 days of receipt of determination. A request for reconsideration must be received by the Deputy General Counsel within 30 days after receipt of the determination. Such a request must be sent to the same address as provided for in paragraph (a) of this section and provide the substantial new evidence or identify the errors in calculation. Such reconsideration will not extend to determinations concerning the law, except as it may have been applied to the facts. A request for reconsideration will be acted on within 30 days from the time it is received. If a request for reconsideration is made, the six month period referred to in section 330(b)(1) and section 1502(e)(2)(A) will commence from the date the requester receives DoD's denial of the request for reconsideration.

(j) *Finality of adjudication.* An adjudication of a request for indemnification constitutes final administrative disposition of such a request, except in the case of a request for reconsideration under paragraph (i) of this section, in which case a denial of the request for reconsideration constitutes final administrative disposition of the request.

Dated: December 2, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–29367 Filed 12–6–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of the Secretary of the Interior

43 CFR Part 49

Bureau of Land Management

43 CFR Part 8360

Fish and Wildlife Service

50 CFR Part 27

[Docket NPS–2016–0003; FWS–93261, FXRS12630900000, FF09R81000, 167; BOR–RR83530000, 178R5065C6, RX.59389832.1009676; BLM–17X.LLW0240000.L10500000.PC0000.LXSIPALE0000; NPS–GPO Deposit Account 4311H2]

RIN 1093–AA16

Paleontological Resources Preservation

AGENCY: Bureau of Land Management, Bureau of Reclamation, National Park Service, U.S. Fish and Wildlife Service; Interior.

ACTION: Proposed rule.

SUMMARY: The Department of the Interior (DOI) proposes to promulgate regulations under the Paleontological Resources Preservation Act. Implementation of the proposed rule would preserve, manage, and protect paleontological resources on lands administered by the Bureau of Land Management, the Bureau of Reclamation, the National Park Service, and the U.S. Fish and Wildlife Service and ensure that these federally owned resources are available for current and future generations to enjoy as part of America's national heritage. The proposed rule would address the management, collection, and curation of paleontological resources from federal lands using scientific principles and expertise, including collection in accordance with permits; curation in an approved repository; and maintenance of confidentiality of specific locality data. The Paleontological Resources Preservation Act authorizes civil and criminal penalties for illegal collecting, damaging, otherwise altering or defacing, or for selling paleontological resources, and the proposed rule further details the processes related to the civil penalties, including hearing requests and appeals of the violation or the amount of the civil penalties.

DATES: Comments on the proposed rule must be received by February 6, 2017. Comments on the information collection requirements must be received by January 6, 2017.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1093–AA16, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. NPS–2016–0003.
- *Mail to:* Julia Brunner, Geologic Resources Division, National Park Service, P. O. Box 25287 Denver, CO 80225–0287.

Instructions: All submissions received must include the RIN for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Please make comments on the proposed rule as specific as possible, confine them to issues pertinent to the proposed rule, and explain the reason for any recommended changes. Where possible, comments should reference the specific section or paragraph of the proposed rule that is being addressed. DOI may not necessarily consider or include in the administrative record for the final rule comments that are received after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments on the Information Collection Aspects of the Proposed Rule: You may review the Information Collection Request online at *http://www.reginfo.gov.* Follow the instructions to review DOI collections under review by OMB. Send comments (identified by RIN 1093–AA16) specific to the information collection aspects of this proposed rule to:

- Desk Officer for the Department of the Interior at OMB–OIRA at (202) 295–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email); and
- Jeffrey Parrillo, Office of the Secretary, Departmental Information Collection Clearance Lead, Department of the Interior, 1849 C Street NW., Mailstop MIB–7056, Washington, DC 20240 (mail); or *jeffrey_parrillo@ios.doi.gov* (email).

System of Records Notice: The Privacy Act of 1974 (5 U.S.C. 552) protects the information submitted in accordance with this part. A System of Records Notice is being developed and will be published in the **Federal Register**.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and search for Docket No. NPS–2016–0003.

FOR FURTHER INFORMATION CONTACT: Julia F. Brunner, Geologic Resources Division, National Park Service, by telephone: (303) 969–2012 or email: *Julia_F_Brunner@nps.gov.* Persons who use a telecommunications device for deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background

In 1999, the Senate Interior Appropriations Subcommittee requested that DOI, the U.S. Department of Agriculture (USDA) Forest Service (FS), and the Smithsonian Institution prepare a report on fossil resource management on federal lands (see Sen. Rep. 105–227, at 60 (1998)). The request directed these entities to analyze (1) the need for a unified federal policy for the collection, storage, and preservation of fossils; (2) the need for standards that would maximize the availability of fossils for scientific study; and (3) the effectiveness of current methods for storing and preserving fossils collected from federal lands. During the course of preparing the report, the agencies held a public meeting to gather public input. The DOI report to Congress, ''Assessment of Fossil Management of Federal and Indian Lands,'' was published in May 2000.

After the report was released, the Paleontological Resources Preservation Act (PRPA) was introduced in the 107th Congress. PRPA was modeled after the Archaeological Resources Protection Act of 1979, as amended (16 U.S.C. 470aa–470mm), and emphasized the recommendations and guiding principles in the May 2000 report. The legislation was reintroduced in subsequent Congresses through the 111th Congress when it was included as a subtitle in the Omnibus Public Land Management Act, which became law on March 30, 2009. Legislative history [1] demonstrates that PRPA, which is now codified at 16 U.S.C. 470aaa–aaa–11, was enacted to preserve paleontological resources for current and future generations because these resources are non-renewable and are an irreplaceable part of America's heritage. PRPA requires that implementation be coordinated between the Secretaries of the Interior and Agriculture (16 U.S.C. 470aaa–1).

II. Development of the Proposed Rule

PRPA requires DOI and USDA to issue regulations as appropriate to carry out the law. Accordingly, DOI and USDA formed an interagency coordination team in April 2009 to draft the proposed regulations. The interagency coordination team included paleontology and archaeology program leads and regulatory specialists from the Bureau of Land Management (BLM), the National Park Service (NPS), the Bureau of Reclamation (Reclamation), the U.S. Fish and Wildlife Service (FWS) (the bureaus), and the FS.

On May 23, 2013, the FS published a proposed rule that would implement PRPA with respect to National Forest System lands (78 FR 30810). On April 17, 2015, the FS published these regulations as final (80 FR 21588).

III. Section-by-Section Analysis of the Proposed Rule

This proposed rule would address management of paleontological resources on federal lands under the jurisdiction of the Secretary of the Interior, and managed by BLM, Reclamation, NPS, and FWS. The proposed rule would amend title 43 of the Code of Federal Regulations (CFR) by adding a new part 49 entitled ''Paleontological Resources Preservation.'' In accordance with 16 U.S.C. 470aaa–1, the proposed rule would outline how the four bureaus would manage, protect, and preserve paleontological resources on federal land using scientific principles and expertise. Most of the proposed rule, specifically subparts A through H, would apply to all four bureaus. The only exception is subpart I, which would apply only to BLM and Reclamation, governing casual collecting (collecting common invertebrate and plant paleontological resources without a permit) on certain lands administered by those bureaus. PRPA does not allow casual collecting in areas administered by NPS or FWS, and therefore subpart I would not apply to these two bureaus. The following is a section-by-section analysis of subparts A through I.

Managing, Protecting, and Preserving Paleontological Resources (Subpart A)

What does this part do (§ 49.1)?

Proposed § 49.1 would restate the purposes of PRPA and summarize the contents of the proposed rule.

What terms are used in this part (§ 49.5)?

Proposed § 49.5 would define certain terms used in the proposed rule. The bureaus believe that most of the terms are readily understood, but discuss the following in more detail below:

Associated records would mean original records or copies of those records, in the context of collections. If original records are not available for some reason, copies of those records are acceptable. Associated records would include primary, public, and administrative records.

Authorized officer would mean the bureau director or employees to whom the Secretary of the Interior has delegated authority to make a decision or to take action, or both, under PRPA. Bureaus may have multiple authorized officers. The authorized officer consults as appropriate with bureau technical specialists, outside experts, bureau partners, museum curators, or others in making decisions and taking action.

Collection would mean paleontological resources removed from geological context or taken from federal lands and any associated records, consistent with the definition of museum property in Part 411 of the Departmental Manual (411 DM). Because permits may be issued only to further paleontological knowledge, public education, or management of paleontological resources, any collections made under those permits should likewise further these goals. Such collections would be deposited in an approved repository. Paleontological resources that are determined by the authorized officer as not furthering or no longer furthering paleontological knowledge, public education, or management of paleontological resources (such as resources that lack provenience or are overly redundant) may, nevertheless, because they are still of paleontological interest and provide information about the history of life on earth, be assigned to project or working

[1] S. 2727: 148 Cong. Rec. S. 6708–6709 (2002) (Statement of Sen. Akaka); S. 546: S. Rep. 108–93 (2003); S. 263: S. Rep. 109–36 (2005); S. 320: 153 Cong. Rec. S. 691–693 (2007) (Statement of Sen. Akaka) and S. Rep. 110–18 (2007); H.R. 554: H. Rep. 110–670, Part 1; and S. 22: 155 Cong. Rec. S. 426 (2009) (Statement of Sen. Akaka).

collections, including non-museum collections.

Curatorial services would mean managing and preserving a museum collection over the long term according to DOI (currently 411 DM) and bureau museum and archival standards and practices.

Nature would mean physical features, identifications, or attributes of the paleontological resource. Including this definition in the proposed regulations would clarify the type of information that PRPA exempts from disclosure.

Paleontological resources would mean any fossilized remains, traces, or imprints of organisms preserved in or on the Earth's crust, except for:

(1) Those that are found in an archaeological context and are an archaeological resource as defined in section 3(1) of the Archaeological Resources Protection Act of 1979 (16 U.S.C. 470bb(1)); or

(2) Cultural items, as defined in section 2 of the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001 *et seq.*); or

(3) Resources determined in writing by the authorized officer to lack paleontological interest or not provide information about history of life on earth, based on scientific and other management considerations.

Thus, under PRPA and the proposed regulation, fossils are ''paleontological resources'' unless they are found in an archaeological context and are archaeological resources, or are cultural items under the Native American Graves Protection and Repatriation Act, or are determined by an authorized officer to lack paleontological interest or not provide information about the history of life on earth.

An example of a fossil that is found in an archaeological context and is therefore an archaeological resource would be a fossil that was collected by prehistoric peoples and is now part of an archaeological site. In this case, the fossil has been removed from its original geological context and is now important primarily for its archaeological informational value. A fossil found in an archaeological context is not a paleontological resource under PRPA or the proposed rule, but may still have scientific value for paleontological investigations and be protected under other authorities. Fossils that are merely in geographical proximity to archaeological resources but are not necessarily in an archaeological context, are therefore not necessarily archaeological resources.

Fossils that the authorized officer determines to not have paleontological interest or not provide information about the history of life on earth, such as fossil fuel deposits or limestone units, would not be considered paleontological resources under PRPA or the proposed rule, although they would remain subject to other laws and regulations. For example, fossils on NPS-administered lands that are not considered paleontological resources would still be protected as natural and cultural resources under the NPS Organic Act of 1916, NPS regulations, and NPS policies. As another example, fossils on BLM-administered lands that are not considered paleontological resources would still be subject to consideration under the Federal Land Policy and Management Act of 1976 (FLPMA), thus allowing BLM to track and report scientific activities, such as research on non-vertebrate microfossils, without requiring that those fossils be managed as paleontological resources or otherwise be subject to PRPA.

Petrified wood is managed as a paleontological resource when on or from lands administered by NPS, Reclamation, and FWS. On lands administered by BLM, petrified wood (defined by the Petrified Wood Act of 1962, Pub. L. 87–713, 76 Stat. 652, Sept. 28, 1962 as agatized, opalized, petrified, or silicified wood, or any material formed by the replacement of wood by silica or other matter, and identified as a mineral material under the Materials Act of 1947) is subject to commercial sale at 43 CFR part 3600 and free use regulations at 43 CFR part 3622. Therefore, on BLM lands, petrified wood may be managed as a paleontological resource, but the savings provisions in PRPA (16 U.S.C. 470aaa–10) prevent the imposition of additional restrictions on the sale or free use of petrified wood. When it is not subject to sale or free use, petrified wood on BLM-administered lands may be managed as a paleontological resource and/or under the authority of FLPMA.

Geological units including but not limited to limestones, diatomites, chalk beds, and fossil soils (*i.e.,* paleosols) would not be considered paleontological resources under the proposed rule. However, the occurrence of discrete paleontological resources within geological units would be considered paleontological resources and, therefore, subject to PRPA and the proposed rule. Determinations about whether a fossil is or is not a paleontological resource would be committed to the authorized officer's discretion, based on scientific or other management considerations. A determination that a fossil is or is not a paleontological resource may be reversed at a later time, at the authorized officer's discretion, based on scientific or other management considerations.

Fossils such as conodonts and nonvertebrate microfossils would be considered paleontological resources when they, as part of a scientific research design, provide critical information toward the understanding of geological units, biological evolution, climate change, and other scientific questions. However, in accordance with section 6311 of PRPA, the proposed rule would not require a permit for the collection of conodonts or nonvertebrate microfossils in association with authorized oil, gas, geothermal, or other minerals activities that are permitted under other authorities. Casual collection of conodonts or nonvertebrate microfossils may be permissible on certain BLM- or Reclamation-managed lands consistent with the limitations defined in subpart I of the proposed rule. Bureaus may individually determine that certain conodonts or nonvertebrate microfossils lack paleontological interest and therefore are not paleontological resources on all or on portions of land they administer.

When paleontological resources on certain BLM- and Reclamation-managed lands are common plant or invertebrate fossils, they may be casually collected in compliance with subpart I of the proposed rule. They are still paleontological resources (meaning that they have paleontological interest and provide information about the history of life on earth), but PRPA authorizes the limited collection of these resources on lands administered by BLM and Reclamation where such collection is consistent with the laws governing the management of those lands, PRPA, and subpart I of the proposed rule.

Paleontological site would mean a locality, location, or area where a paleontological resource is found; the site can be relatively small or large. The definition of paleontological site is never synonymous with ''archaeological site'' as used in 43 CFR part 7.

Working collection would mean paleontological resource collections that are not intended for long-term preservation and care as museum collections. Departmental policy on working collections is expanded in Section 1.7, 411 DM, *Identifying and Managing Museum Property.*

Does this part affect existing authorities (§ 49.10)?

Proposed § 49.10 would state that the proposed rule preserves the authority of the Secretary of the Interior under this and other laws and regulations to manage, protect, and preserve

paleontological resources on federal land under the jurisdiction of the Secretary. PRPA and the proposed rule complement the bureaus' other authorities for paleontological resource management. The proposed rule would be consistent with existing bureau practices and would clarify the responsibilities of the bureaus to preserve, protect, and manage paleontological resources.

When does this part not apply (§ 49.15)?

Proposed § 49.15 would state that the proposed rule does not impose additional requirements on activities permitted under the general mining or mineral laws, does not apply to Indian land, and does not apply to land other than federal land as defined in the proposed rule. This is consistent with the savings provisions of the PRPA. This section means that the bureaus will not add requirements under PRPA and the proposed rule to mining- and mineral-related permits. For example, the bureaus may not cite PRPA or the proposed rule in the list of mitigation measures that is attached to an approved mining plan of operations. However, because PRPA and the proposed rule do not limit the applicability of other legal authorities such as the Mining in the Parks Act and FLPMA, the bureaus may continue to cite those other authorities as protection for paleontological resources when authorizing or conditioning land or resource uses under those authorities. This section would also clarify that, under PRPA, the word ''reclamation'' means reclamation in the context of mining and mineral activities and not the broader context of all federal reclamation activities.

Does this part create new rights or entitlements (§ 49.20)?

Proposed § 49.20 would state that the proposed rule would not create a right or standing to file suit for persons who are not officers or employees of the United States acting in that capacity. It would repeat section 6311 of PRPA (16 U.S.C. 470aaa–10) for public notice and clarity.

What information concerning the nature and specific location of paleontological resources is confidential (§ 49.25)?

Proposed § 49.25 would implement the provision in PRPA that exempts information about the nature and specific location of a paleontological resource from disclosure under the Freedom of Information Act and any other law unless the authorized officer determines that disclosure would: (1) Further the purposes of PRPA; (2) not create risk of harm to or theft or destruction of the resource or site containing the resource; and (3) be in accordance with other applicable laws. This proposed section would also require a written agreement between the bureau and the party seeking the disclosure, which would ensure that the recipient of the disclosure does not publicly distribute or otherwise release, disclose, or share the information. For example, a partner repository would not be permitted to post specific locality information on-line, but if authorized to do so in a written agreement could still share such information for educational or scientific uses that would not create harm or risk to the resource. The agreement to maintain confidentiality of released information would ensure that the release of confidential information in one situation would not trigger the requirement of the bureau to release that same information to other requestors.

How will the bureaus conduct inventory, monitoring, and preservation activities (§ 49.30)?

Proposed § 49.30 would explain that the bureaus will conduct inventory, monitoring, and preservation activities based upon scientific and resource management principles and practices, and clarify that these activities are undertaken by each bureau internally or may be coordinated with other agencies, non-federal partners, scientists, and the general public where appropriate and practical. Such coordination might take place through mechanisms such as agreements, permits, grants, citizen science efforts, or other arrangements. For public notice and clarity, § 49.30 would repeat section 6302 of PRPA, 16 U.S.C. 470aaa–1.

How will the bureaus foster public education and awareness (§ 49.35)?

Proposed § 49.35 would explain that the bureaus will establish a program to increase public awareness, coordinated with other agencies, non-federal partners, scientists, and the general public where appropriate and practical. National Fossil Day, an annual multi-agency and multi-partner event, is a successful example of how the bureaus are already working to increase public awareness. For public notice and clarity, § 49.35 would repeat section 6303 of PRPA, 16 U.S.C. 470aaa–2.

When may the bureaus restrict access to an area (§ 49.40)?

Proposed § 49.40(a) would state that the authorized officer may restrict access to or close areas to collection to protect resources or provide for public safety. For public notice and clarity, paragraph (a) would repeat section 6304(e) of PRPA, 16 U.S.C. 470aaa–3(e). Proposed § 49.40(b) would clarify that other authorities may also be used to restrict access to or close areas in order to preserve or protect paleontological resources or provide for public safety. This authority supplements the bureaus' existing authority and procedures for restricting access to areas or closing areas to collection (see BLM regulations at 43 CFR 8364.1; Reclamation regulations at 43 CFR 423.29; FWS regulations at 50 CFR 25.21; and NPS regulations at 36 CFR 1.5).

Paleontological Resources Permitting—Requirements, Modifications, and Appeals (Subpart B)

Since 1906, the bureaus have permitted the collection of paleontological resources under various legal and regulatory authorities. Permitting will continue under PRPA and the proposed regulations.

When is a permit required on federal land (§ 49.50)?

Proposed § 49.50 would clarify when a permit is required and who must have a permit. A permit would be required for collecting paleontological resources or disturbing paleontological sites except for casual collecting on certain lands managed by BLM or Reclamation where casual collecting is allowed. The conditions for casual collecting are defined in subpart I of this proposed rule. Proposed § 49.50(b) states a permit may be required by a bureau for paleontological investigative activities that do not involve collection or disturbance in order to track and report on scientific activities or for other purposes. Proposed § 49.50(c) states a permit would be required for federal employees to disturb paleontological sites or collect paleontological resources although bureaus may implement this requirement on a programmatic basis, consistent with their internal processes. The bureau personnel so authorized must meet the professional requirements defined in § 49.60 of the proposed rule, and have experience appropriate to the planned work. The approval must be issued by the bureau managing the land. All collected materials are the property of the Federal Government, and must be managed and curated consistent with the requirements of subpart C of the proposed rule.

Who can receive a permit (§ 49.55)?

Proposed § 49.55 would establish that applicants who meet the qualification requirements of proposed § 49.60, provide a complete application, and

meet the permit issuance criteria may receive a permit. This proposed section would not affect valid permits issued before the effective date of the proposed rule.

What criteria must a permit applicant meet (§ 49.60)?

Proposed § 49.60(a)(1)–(4) would describe qualifications needed for an applicant to receive a permit. PRPA requires the bureaus to ensure that proposed work under a permit will further paleontological knowledge or public education and that the applicant is qualified to carry out the permitted activity. In order to accomplish both requirements, the proposed regulations would require the applicant and others overseeing work under the permit to have experience and qualifications in paleontology appropriate to the tasks they are to perform. For the applicant, an advanced degree in paleontology or equivalent experience and prior field experience has been the baseline for this requirement for all of the bureaus for more than 20 years and is consistent with similar policy for archaeology permits that are authorized under the Archaeological Resources Protection Act of 1979. The authorized officer may grant a permit to an applicant who lacks an advanced degree or specialized experience if the authorized officer is satisfied that the applicant's education and experience are sufficient to carry out the work that is proposed. The authorized officer may grant the permit, grant the permit with limitations, or deny the permit based on the applicant's education, experience, and past performance, and qualifications of persons named in the application as overseeing work.

Proposed § 49.60(b) states that past performance will also be considered, and includes any aspect that could affect performance under the permit being applied for. This would include compliance with previous permits, relevant civil or criminal violations, or relevant indictments or charges.

Where must a permit application be filed and what information must it include (§ 49.65)?

In order to ensure consistency among bureaus, proposed § 49.65 lists the information that a permit applicant is required to provide before a bureau can issue a permit under this subpart. Proposed § 49.65(a) would require permit applicants to submit an application to the bureau that administers the federal land where the proposed activity would be conducted. For activities on lands administered by BLM, Reclamation, and FWS, permit applicants would use DI Form 9002 (*Paleontological Resource Use Permit Application*). For activities on lands administered by NPS, permit applicants would use NPS's Research Permit and Reporting System (RPRS). This paragraph would also clarify that it is the permit applicant's responsibility to determine which bureau has jurisdiction, use that bureau's permit application form and process, and respond to that bureau's requests for information in a timely manner.

Proposed § 49.65(b) would describe the information requirements that the permit application forms would include.

How will a bureau make a decision about a permit application (§ 49.70)?

Proposed § 49.70(a) and (b) would identify how a bureau evaluates and decides on a permit application. Because permit approval would be partially based on whether the proposed repository for the collection under the permit would meet the standards of 411 DM, proposed § 49.70(c) would require the authorized officer to work with the permit applicant and proposed repository to decide whether to approve that repository for the collection. The phrase ''the authorized officer may'' means that the authorized officer has discretion to approve or deny a permit based on information provided by the applicant, past and present performance, management considerations, bureau policy, and other considerations.

What terms and conditions will a permit contain (§ 49.75)?

Proposed § 49.75(a) would specify that a permit would include but not be limited to certain terms and conditions. Section 6304 of PRPA lists three required permit terms and conditions. The proposed rule would require additional terms and conditions in order to enhance consistency among bureaus as emphasized by section 6302(b) of PRPA. For approved activities on lands administered by BLM, Reclamation, and FWS, the authorized officer would issue the permit using DI Form 9003 (*Paleontological Resource Use Permit*). For approved activities on lands administered by NPS, the authorized officer would issue the permit under the NPS RPRS.

Proposed § 49.75(a)(3) would clarify that the permittee is responsible for ensuring that the resource site or recovered paleontological materials are not put at risk as a result of work that is done under the permit. For example, if fossils are exposed by collection or excavation, they must be protected from damage, theft, or other harm for the period they are exposed to risk. Additionally, the permit would not authorize permittees to modify the environment around an area of work. For example, permittees would not be allowed to cut trees, create roads, or grade parking areas.

Proposed § 49.75(a)(8) would require a permittee to report suspected resource damage or theft to the authorized officer after learning of such damage or theft. Such reporting should be done as soon as possible, but in all cases must be done within 48 hours. Based on the bureaus' experience, 48 hours is a reasonable timeframe for such reporting.

Proposed § 49.75(a)(9) would clarify that collections made under a permit must be deposited in the approved repository, and that the permittee must notify the bureau of the deposit. The notification of deposit is required because the bureau must know the nature, condition, and location of federally owned paleontological resources in order to meet PRPA's mandate to manage these resources using scientific principles and expertise, and to meet Departmental museum management requirements. Documentation of the transfer of paleontological resources from the care of the permittee to the care of the approved repository is necessary so that the bureau, the permittee, and the approved repository will each know which party is responsible for the care and management of the paleontological collection.

To avoid a situation where bureaus or repositories could have large collections of paleontological resources that are costly to maintain or no longer contribute to science, the proposed rule would allow the authorized officer to determine that specimens that are found to be redundant, lack adequate associated data, or otherwise are determined not to further paleontological knowledge, public education, or management of paleontological resources may be removed from museum collections and placed into working collections.

Proposed § 49.75(a)(10) would clarify that all paleontological resources collected under a permit remain federal property. The resources that are not collected, but instead are left *in situ* or otherwise are left in the field by the permittee, also remain federal property. Removal of any paleontological resources from federal land not in accordance with this subpart may constitute theft of federal property.

Proposed § 49.75(a)(12) would state that the permittee is responsible for the costs of carrying out the permitted

activity, including curation costs, consistent with specific or programmatic direction from the authorized officer.

Proposed § 49.75(a)(13) would require a permittee to provide reports as required by the bureau in the permit. The permittee will ensure that reports are submitted in a timely fashion and contain the information necessary to ensure accountability for federal resources. For activities that were conducted on lands administered by BLM, Reclamation, or FWS, reports would be submitted using DI Form 9005 (*Paleontological Permit Report Cover Sheet*) or DI Form 9006 (*Paleontology Consulting Report Summary Sheet*). For activities that were conducted on lands administered by NPS, reports would be submitted under the NPS RPRS. Proposed § 49.75(a)(16) would state that a permittee may not transfer the permit to another person.

Proposed § 49.75(b) would authorize the bureau to hold a permittee responsible for complying with applicable permit terms and conditions after it has expired or been cancelled, suspended, or revoked. Like all terms and conditions, this requirement would be enforceable under the criminal and civil penalties provision of this part, and would enable bureaus to preserve paleontological resources and maintain accountability by requiring that affected resource sites be left in a good condition, collections be transferred to the approved repository in a timely manner, that associated records be produced, and that reports be submitted, regardless of the status of the permit.

Proposed § 49.75(c) would provide that the authorized officer may include in the permit additional terms and conditions necessary to carry out the purposes of this part.

Proposed § 49.75(d) would provide that for activities approved on lands administered by BLM or Reclamation, the authorized officer may provide a permittee with DI Form 9007 (*Paleontology Work Notice to Proceed*), which contains site-specific guidance and stipulations for the permittee. The Notice to Proceed is considered part of or an addendum to the permit. Proposed § 49.75(e) would provide that persons who do not comply with the terms of a permit issued under this part may be subject to civil or criminal penalties.

When and how may a permit be modified, suspended, revoked, or cancelled (§ 49.80)?

Proposed § 49.80 would identify when and how a permit may be modified, suspended, revoked, or cancelled. The authorized officer would notify a permittee of such actions verbally or in writing. Any verbal notification would be confirmed by a written order delivered as soon as practicable after issuance of the verbal order. The notification would be immediately effective upon the permittee's receipt of the verbal or written notification, whichever is received first.

Proposed § 49.80(a) would identify when a permit may be modified. Common permit modifications may include changing the duration of a permit, changing personnel that are named on a permit, changing the geographic area that is authorized under a permit, making minor modifications to the stratigraphic context or scope of work, or adding or altering supplemental terms and conditions to a permit. These modifications may be requested by the permittee or initiated by the bureau. The authorized officer may issue a new permit or require the permittee to submit a new application when a modification would substantially change the scope of the existing permit.

Proposed § 49.80(b) would identify when activities under a permit may be suspended. Common reasons for a suspension include the discovery of potential resource conflicts, failure of the permittee to follow terms and conditions, resource protection issues, or budget or staffing concerns. A suspension would last no longer than 45 days, and may be lifted by the authorized officer when the reasons for suspension no longer apply, or when conditions for lifting a suspension have been met. After 45 days, if the circumstances prompting the suspension have not been resolved, the suspension will end and the authorized officer may modify, revoke, or cancel the permit, as appropriate to the specific circumstance.

Proposed § 49.80(c) would identify when a permit may be revoked. A permit will be revoked when, for example, a permittee fails to follow the terms and conditions of a permit, is charged with a civil or criminal violation under PRPA or under other applicable laws, or is found ineligible to hold a paleontology permit.

Proposed § 49.80(d) would identify when a permit may be cancelled. Cancellation would differ from revocation in that it would terminate a permit for reasons that do not relate to improper or poor performance on the part of the permittee. Cancellation is not a negative action and should not be cause to deny a future permit to the applicant. Cancellation may occur when administrative or resource issues warrant, and may follow a 45-day suspension, or may occur without a suspension occurring. A permittee may request a permit to be cancelled for any reason, or the bureau may need to cancel the permit for administrative or management reasons. Although PRPA does not specifically reference permit cancellation, the proposed regulations include this option because permit cancellation is a form of permit modification (changing the end date of the permit) and is therefore within the scope of PRPA.

Proposed § 49.80(e) would specify that the authorized officer will notify a permittee of the modification, suspension, revocation, or cancellation either verbally or in writing. Proposed § 49.80(f) would specify that notifications of modification, suspension, revocation, or cancellation are effective upon the permittee's receipt of the written notification.

Can a permit-related decision be appealed (§ 49.85)?

Authorized officers have discretion to make permit-related decisions based on information provided by the applicant, past and present performance, management considerations, bureau policy, and other considerations. Proposed § 49.85 would state that permit-related decisions may be appealed.

What is the process for appealing a permit-related decision (§ 49.90)?

Proposed § 49.90 would specify the processes for appealing permit-related decisions. BLM and FWS each have applicable regulations, and NPS already has a process in place. Reclamation will develop an appeals process for permit decisions and will document the process in Reclamation's system of written directives. The appeals process may include a review by the applicable Reclamation Regional Director, followed by appeal to Reclamation's Commissioner, similar to the process in place for land use decisions found at 43 CFR part 429.

Has OMB approved the information collection provisions of this part (§ 49.95)?

Proposed § 49.95 would describe the information collection status of this part.

Management of Paleontological Resource Collections (Subpart C)

The proposed requirements provided in subpart C are consistent with requirements provided for

archaeological collections at 36 CFR part 79.

Where are collections deposited (§ 49.200)?

Proposed § 49.200 would clarify that collections made under a permit issued under this part must be deposited in a repository approved by the authorized officer. Collections made prior to the effective date of the proposed rule would be subject to the terms and conditions of the original collection permit or agreement, which is also consistent with guidance in current DOI museum policy.

How will bureaus approve a repository for a collection made under this part (§ 49.205)?

Proposed § 49.205(a) would grant the authorized officer discretion to approve a repository for a collection based on several factors, including appropriate scope of collections, qualified curation staff, adequate public access, compliance with DOI museum collection standards, and consistency with bureau management goals. Approval of a repository is necessary for both federal and non-federal repositories.

Proposed § 49.205(b) would clarify that when the authorized officer approves a repository for the collection, that repository will be listed in the approved permit and will remain approved to curate the collection unless the authorized officer determines that any one of the considerations in paragraph (a) of this section is no longer met. In that case, the repository would be notified and would have a reasonable amount of time to:

(1) Correct the deficiency;

(2) Move the collection to another approved repository; or

(3) Take other actions the authorized officer requests.

In situations involving movement of the collection to another approved repository, the first repository would likely ship the collection to the second repository in accordance with the authorized officer's instructions. The bureau would then close the deposit agreement with the first repository and enter into a new agreement with the second repository.

What is the process for depositing the collection at the approved repository (§ 49.210)?

Proposed § 49.210 would clarify the process for depositing paleontological collections at the approved repository. Under proposed § 49.210(a), the authorized officer would work with the permittee and approved repository, using scientific principles and expertise, to ensure that the collection is complete and that the content of the collection would further paleontological knowledge, public education, or management of paleontological resources. In addition, the authorized officer would review any existing agreement between the bureau and the approved repository to determine if that agreement adequately addresses requirements that are specific to the collection and either develop a new agreement, or amend an existing agreement, if an adequate agreement does not exist.

Under proposed § 49.210(b), the permittee or the repository would submit DI Form 9008 (*Repository Receipt for Collections (Paleontology)*) to the authorized officer. This form would include but not be limited to a certification by the permittee that the collection was deposited at the repository, and a certification by the approved repository's authorized official that the collection has been received.

For repository managers concerned that the curation requirements of PRPA and the proposed rule could lead to unrealistic or burdensome curation requirements, the proposed rule addresses these concerns in three ways. First, a repository may agree or decline to curate a collection of paleontological resources. Second, the authorized officer is ultimately responsible for determining the content of the collection, with input from the permittee and the repository, and ensuring that the collection meets bureau management goals. Third, the proposed rule specifies that the standard for collection under permit and deposit into an approved repository is that the collection furthers paleontological knowledge, public education, or management goals for paleontological resources. If a proposed collection would not meet this standard, then the collection should not be permitted. If the authorized officer determines that a collection formerly met this standard but no longer does, then part or all of the collection may be removed from the approved repository, transferred to a working collection, or managed in other ways consistent with DOI standards in 411 DM and bureau museum management procedures. Note that, in such a circumstance, that collection is still comprised of paleontological resources. If the specimens in a collection are determined by the authorized officer to no longer have paleontological interest or provide information about the history of life on earth, then they are not paleontological resources as defined in PRPA and the proposed rule. All of these aspects of the proposed rule should ameliorate the concerns of repository managers that the requirements in PRPA would be burdensome.

What terms and conditions must the agreement between the bureau and approved repository contain (§ 49.215)?

Proposed § 49.215 would specify the terms and conditions that must be included in an agreement between the bureau and the repository. The terms and conditions provided in this section are consistent with 411 DM. Several of these terms and conditions are addressed below for further clarification.

First, proposed § 49.215(a)(2) would clarify that the Federal Government retains ownership of all paleontological resources collected under a permit, regardless of where the resources reside, who discovered or collected them, or who assumes administrative responsibility for their care. Bureaus may transfer all or portions of collections of paleontological resources to other federal bureaus (including the Smithsonian) either by loan or by administrative transfer without changing the fact that they are owned by the Federal Government.

Proposed § 49.215(a)(6) requires that agreements describe any special procedures or restrictions for access to controlled property, consumptive use, reproduction, or curatorial services, including loans. These terms are all defined in 411 DM.

Proposed § 49.215(a)(11) would clarify that one of the terms and conditions is a statement that employees cannot take any action that results in collection encumbrance, seizure, theft, damage, or other issues, and closely follows 36 CFR part 79 and DOI policy in 411 DM. The prohibition against damaging a collection does not prevent consumptive use that is approved by the bureau in a permit, agreement, or other written documentation.

What are the standards for managing the collections (§ 49.220)?

Proposed § 49.220 would provide standards for managing collections made under this part that are consistent with DOI policy for the management of museum collections found at 411 DM. Particular provisions of this proposed section are addressed below.

Proposed § 49.220(a)(1) would make collections and locality data available subject to the confidentiality provisions of the proposed rule and PRPA.

Proposed § 49.220(b) would authorize repositories to charge reasonable fees, consistent with applicable law, to cover their costs of making federal paleontological resources available to the public.

Prohibited Acts (Subpart D)

What acts are prohibited (§ 49.300)?

For public notice and clarity, proposed § 49.300 would restate the prohibitions contained in section 6306 of PRPA (16 U.S.C. 470aaa–5). Under PRPA and this section, a person may not:

(a) Excavate, remove, damage, or otherwise alter or deface or attempt to excavate, remove, damage, or otherwise alter or deface any paleontological resource located on federal land unless this activity is conducted in accordance with PRPA and this part. For example, this would prohibit moving or relocating a paleontological resource from its *in situ* geologic context without authorization under the proposed rule. Such authorization would be in the form of a permit or casual collection consistent with subpart I of this part.

(b) Exchange, transport, export, receive, or offer to exchange, transport, export, or receive any paleontological resource if the person knew or should have known such resource to have been excavated or removed from federal land in violation of any provision, rule, regulation, law, ordinance, or permit in effect under federal law, including PRPA and this part.

(c) Sell or purchase or offer to sell or purchase any paleontological resource if the person knew or should have known such resource to have been excavated, removed, sold, purchased, exchanged, transported, or received from federal land.

(d) Make or submit any false record, account, or label for, or any false identification of, any paleontological resource excavated or removed from federal land. This provision would apply when a person knew or should have known that information was false, or when there was intent to deceive, misrepresent, or mislead.

Criminal Penalties (Subpart E)

What criminal penalties apply to violations of this part (§ 49.400)?

Proposed § 49.400 would describe what criminal penalties apply to persons who commit prohibited acts under this part. Bureaus may utilize other authorities to issue citations for criminal violations involving paleontological resources.

Proposed § 49.400(a) would state that criminal penalties would not apply with respect to paleontological resources in the lawful possession of a person on or before March 30, 2009, which is the date that PRPA was enacted.

Proposed § 49.400(b) would authorize penalties upon conviction for persons who knowingly violate or counsel, procure, solicit, or employ another person to violate subpart D of this proposed rule. If the value of the paleontological resources involved (which means the sum of the commercial and scientific value of the paleontological resources involved and the cost of response, restoration, and repair of the resources and sites involved) is more than $500, penalties would be assessed in accordance with Title 18 of the U.S. Code and/or may include imprisonment for up to 5 years. If the value of the paleontological resources involved is less than $500, penalties would be assessed in accordance with Title 18 of the U.S. Code and/or may include imprisonment for up to 2 years. A court may award restitution, which may also be called penalties or damages, to the bureau for injuries to paleontological resources, in lieu of or in addition to fines.

Proposed § 49.400(c) would state that the term ''value of the paleontological resources involved'' would be explained in subpart G of this proposed rule.

Proposed § 49.400(d) would state that in the case of a second or subsequent violation by the same person, the amount of the penalties assessed under this subpart may be doubled.

Proposed § 49.400(e) would authorize law enforcement officers to issue citations for minor violations under the bureaus' existing enforcement authorities, such as misdemeanor penalties, rather than relying solely on the criminal penalties provided by PRPA.

Civil Penalties (Subpart F)

When can the authorized officer assess a civil penalty (§ 49.500)?

Proposed § 49.500 would state that the authorized officer may assess a civil penalty upon any person who violates the provisions of the proposed rule or a permit issued under the proposed rule, and that each violation would be considered a separate offense.

How does the authorized officer serve a notice of violation (§ 49.505)?

Proposed § 49.505 would state the authorized officer may serve a notice of violation in person, by certified mail, return receipt requested, or other verifiable delivery method upon a person that the authorized officer believes has committed a violation of the proposed rule.

What is included in the notice of violation (§ 49.510)?

Proposed § 49.510 would describe the contents of a notice of violation.

How is an objection to a notice of violation made and proposed civil penalty made and resolved (§ 49.515)?

Proposed § 49.515 would state that a person who receives a notice of violation and proposed civil penalty has 30 days from the date of receipt in which to file a written objection with the authorized officer. The person must state the reasons for the objection, provide any supporting documentation, and sign the objection.

By written notice, the authorized officer would sustain or deny the objection based on the information in the objection and any information provided upon request. If the authorized officer concludes there was no violation, the objection would be sustained, the notice of violation revoked, and no civil penalty would be assessed. If the authorized officer finds that a violation occurred, the objection would be denied. If the authorized officer finds that a violation occurred but the proposed civil penalty was too high, the objection would be denied in part and sustained in part.

When will the authorized officer issue a final assessment of civil penalty (§ 49.520)?

Proposed § 49.520 would state that if the person who was served with a notice of violation and proposed civil penalty does not file a timely objection, or files a timely objection which is denied, the authorized officer would issue a final assessment of civil penalty.

How will the authorized officer calculate the amount of a proposed and final assessment of civil penalty (§ 49.525)?

Proposed § 49.525 would explain the factors that the authorized officer will take into account when calculating a proposed and a final assessment of civil penalty. For a first violation, the authorized officer considers the factors listed in § 49.525(a) and (b) and assesses a penalty. For example, the penalty might be $1,000.

Under proposed § 49.525(c), penalties for subsequent violations may be doubled. Thus, if a person who has already been assessed a civil penalty for a particular violation commits another prohibited act, the authorized officer may double the penalty for that act. For example, if the penalty for the second prohibited act would be $1,200 under the factors listed in paragraphs (a) and (b) of this section, the authorized officer

would have the discretion to double this penalty and assess the person $2,400. When doubling penalties for subsequent violations, the authorized officer must be mindful of § 49.525(d), which caps penalties at an amount equaling twice the cost of response, restoration, and repair plus twice the cost of scientific or fair market value of the resources (whichever is greater).

Proposed § 49.525(d)(2) authorizes civil penalties for damages to paleontological resources and paleontological sites. If other resources or sites are damaged, the bureaus can utilize their authorities under laws such as the Endangered Species Act, the Archaeological Resources Protection Act, the National Park System Resources Protection Act, and other statutes to pursue separate legal or administrative remedies.

Proposed § 49.525(e) would direct the authorized officer to use proposed subpart G of this proposed rule to determine scientific or commercial values and the cost of response, restoration, and repair.

Proposed § 49.525(f) would state that the final assessment may be equal to, less than, or more than the proposed civil penalty.

How will the authorized officer issue the final assessment of civil penalty (§ 49.530)?

Proposed § 49.530 would state that the authorized officer would serve the final assessment of civil penalty by certified mail, return receipt requested, or another verifiable delivery method. The proposed section would also describe the required content of the final assessment.

What are the options and timeframe to respond to the final assessment of civil penalty (§ 49.535)?

Proposed § 49.535 would provide that a person who receives a final assessment of civil penalty must exercise one of two options within 30 days of the date the assessment is received: (1) Accept the assessment by filing a written notice with the authorized officer or paying the assessed penalty, or (2) file a request for hearing before an administrative law judge with the Departmental Case Hearings Division (DCHD), Office of Hearings and Appeals, DOI in accordance with § 49.535(b). The request for hearing will be dismissed if it is not timely filed with DCHD and may be dismissed if it does not contain all information described in proposed § 49.535(b).

If the person fails to file under either option within 30 days, the assessment will be deemed accepted. Acceptance of the assessment waives the right to hearing.

What procedures govern the DCHD hearing process initiated by a request for hearing on the final assessment (§ 49.540)?

If a person files a request for a hearing with an administrative law judge, proposed § 49.540 would explain the procedures for that hearing.

What will be included in the administrative law judge's decision (§ 49.545)?

Proposed § 49.545 would describe the contents of the administrative law judge's decision and would state that such decision would become effective 31 days from the date of the decision absent a timely appeal of the decision.

How can the administrative law judge's decision be appealed (§ 49.550)?

Proposed § 49.550 would provide the person who filed a request for the hearing with an administrative law judge, as well as the bureau, with the opportunity to appeal that judge's decision by submitting a written dated appeal of the decision to the DOI Office of Hearing and Appeals via certified mail, return receipt requested, or other verifiable delivery method, and would also describe the contents of the appeal documents and the mailing addresses where the appeal documents must be sent.

What procedures govern an appeal of an administrative law judge's decision to the OHA Director (§ 49.555)?

Proposed § 49.555 would state that the appeal to OHA is governed by 43 CFR part 4, subparts A and G, and other provisions of 43 CFR part 4, where applicable.

When must the civil penalty be paid (§ 49.560)?

Proposed § 49.560 would explain decisions that are considered final administrative decisions. A person has 30 days from the date of those final decisions to fully pay the final assessment of civil penalty or agree to a payment schedule.

When may a person assessed a civil penalty seek judicial review (§ 49.565)?

Proposed § 49.565 would explain that, within 30 days of the OHA decision, a person may file a petition for judicial review in the United States District Court for the District of Columbia or in the district where the violation occurred, and that the deadline for payment of the civil penalty will be stayed pending resolution of the judicial review.

What happens if a civil penalty is not paid on time (§ 49.570)?

Proposed § 49.570 would describe the consequences of failing to fully pay the final assessment of civil penalty by the required deadlines.

How will collected civil penalties be used (§ 49.575)?

Proposed § 49.575 would state that civil penalties collected under this subpart are available without further appropriation to the bureau that administers the federal land or paleontological resources that were the subject of the violation, and may be used by the bureau for several purposes, including: Protection, restoration, or repair of the paleontological resources and sites that were the subject of the action, and protection, monitoring, and study of the resources and sites; and provision of educational materials to the public about paleontological resources, paleontological sites, or resource protection; or payment of rewards.

Determining Values and the Costs of Response, Restoration, and Repair (Subpart G).

Proposed subpart G would provide direction on determining values and the cost of response, restoration, and repair under this part. The authorized officer may consult with subject matter experts, such as resource specialists, area specialists, and law enforcement specialists, in determining these values.

What is scientific value (§ 49.600)?

Proposed § 49.600 would describe scientific value. PRPA uses the term ''paleontological value'' in the section on prohibited acts and criminal penalties, and then switches to ''scientific value'' in the section on civil penalties. The bureaus agree that the two terms are synonymous and that for purposes of consistency and clarity only the term ''scientific value'' would be used in the proposed rule.

What is commercial value (§ 49.605)?

Proposed § 49.605 would describe commercial value. PRPA uses the term ''commercial value'' in the section on prohibited acts and criminal penalties, and then switches to ''fair market value'' in the section on civil penalties. The bureaus agree that the two terms are synonymous and for the purposes of consistency and clarity only the term ''commercial value'' would be used in the proposed rule.

What is the cost of response, restoration, and repair (§ 49.610)?

Proposed § 49.610 would define the cost of response, restoration, and repair. In some cases, it may be appropriate for the estimated cost of response, restoration, and repair to be peer reviewed. The values and costs should be determined by paleontologists with appropriate expertise.

Forfeiture and Rewards (Subpart H).

Will a violation lead to forfeiture of a paleontological resource (§ 49.700)?

Proposed § 49.700 would explain when a violation will lead to the forfeiture of paleontological resources. When there are civil or criminal forfeitures, paleontological resources are either returned to, or remain in, the administrative authority of the Federal Government. Where appropriate, the bureau will initiate forfeiture under a cooperative agreement with agencies that have forfeiture regulations.

What rewards may bureaus pay to those who assisted in enforcing this part (§ 49.705)?

Proposed § 49.705 would describe the rewards that may be paid for assistance in enforcing the proposed rule. Proposed § 49.705(a) would establish that the bureau may pay a reward to the person or persons who assist the bureau by furnishing information that leads to a finding of a civil or criminal violation. Rewards will not be paid for the discovery or reporting of a paleontological resource (*i.e.,* there is no bounty for discovering a fossil).

Casual Collection of Common Invertebrate or Plant Paleontological Resources on Bureau of Land Management and Bureau of Reclamation Administered Lands (Subpart I)

Is casual collecting allowed on lands administered by NPS or FWS (§ 49.800)?

Proposed § 49.800 would explain that PRPA does not allow casual collecting in areas managed by NPS or FWS. In those areas, collecting any paleontological resource must be conducted in accordance with a permit issued by NPS or FWS under subpart B of this proposed rule.

Is casual collecting allowed on lands administered by BLM or Reclamation (§ 49.805)?

Under proposed § 49.805(a), casual collecting would continue as currently authorized on lands administered by BLM, except that the PRPA terms ''negligible disturbance'' and ''reasonable amount'' defined under § 49.810 must be followed. Casual collecting will not be allowed on BLM lands that are or become closed to casual collecting, BLM-administered national monuments, BLM-administered national conservation areas, outstanding natural areas, forest reserves, or cooperative management and protection areas, except where the bureau has specifically determined that casual collection would not impair the intent of the preservation designation. Because BLM must ''conserve, protect, and restore [these] nationally significant landscapes that have outstanding cultural, ecological, and scientific values for the benefit of current and future generations,'' the bureau must ensure that these areas would not be negatively affected by casual collecting (establishment of the National Landscape Conservation System, 16 U.S.C. 7202). Closures or restrictions may be short term, long term, or permanent. The BLM is requesting public comment regarding the range of designations listed in § 49.805(a)(2) as prohibiting or restricting casual collection, including whether and why additional designations should be included or currently proposed designations excluded from the list.

Proposed § 49.805(b) would explain that casual collecting of common invertebrate or plant paleontological resources will be allowed on land administered by Reclamation only in locations where Reclamation has established a special use area for casual collecting using processes defined in Reclamation's regulation at 43 CFR part 423, *Public Conduct on Bureau of Reclamation Facilities, Lands, and Waterbodies.* This proposed paragraph would also state that casual collecting is prohibited on Reclamation project land that is administered by NPS or FWS.

Proposed § 49.805(c) would clearly place full responsibility on persons interested in casual collecting to ascertain which bureau manages the land where those persons would like to collect paleontological resources, whether the land is open to casual collecting, and what may be collected in an area, and to obtain information about the managing bureau's casual collecting procedures.

What is casual collecting (§ 49.810)?

Proposed § 49.810(a) would restate the PRPA definition of casual collecting. Proposed § 49.810(a)(1) through (a)(5) would provide specific definitions for the terms used in the PRPA definition.

Under proposed § 49.810(a)(1), only common invertebrate and common plant paleontological resources may be casually collected. Common invertebrate and common plant paleontological resources are invertebrate or plant fossils that have been established by the bureaus, based on available scientific information and current professional standards, as having ordinary occurrence and widespread distribution.

Although these particular resources may be common, they are still paleontological resources as defined in PRPA and the proposed rule. That is, they have paleontological interest and provide information about the history of life on earth.

Not all invertebrate or plant paleontological resources are common. If the resources are not common, they may only be collected under a permit. It may not always be possible for a collector to identify in the field whether a fossil is common. When in doubt, collectors should err on the side of caution and collect only the resources that they know are common. The bureaus may hold a trained amateur, avocational paleontologist, or professional to a higher standard of knowledge than the general public about whether or not a fossil is common.

If a knowledgeable collector makes an unanticipated discovery of an uncommon paleontological resource while casually collecting, that collector shall not collect that resource because he or she is not authorized to do so. Instead, the collector should alert the relevant bureau. If the collector wishes to pursue collection, he or she must obtain a permit to collect the uncommon resource. If the collector does collect the uncommon resource without a permit, that collector may be subject to penalties.

Proposed § 49.810(a)(2) would establish ''reasonable amount'' for casual collecting as 25 pounds per day per collector, not to exceed 100 pounds per year per collector. This proposed definition would also clarify that pooling of multiple daily amounts by one or more collectors to obtain pieces in excess of 25 pounds is not allowed. The bureaus determined that the 25 pounds per day per collector, and the 100 pounds per year per collector, are reasonable amounts based on BLM's long experience with the collecting of petrified wood and other fossils from BLM lands before PRPA was enacted. These amounts represent a balance between PRPA's mandate to allow casual collecting and other laws that require the bureaus to protect and manage other natural and cultural resources.

The proposed prevention of the pooling of multiple daily amounts

would add clarification and be consistent with existing BLM regulations at 43 CFR 3622.4 governing the collecting of petrified wood.

The bureaus considered defining ''reasonable amount'' as equaling two quarts instead of 25 pounds, but decided that the use of a weight limit, rather than a size limit, is more consistent with existing collection standards that are already understood by the public and the bureaus.

Proposed § 49.810(a)(3) would clarify that ''negligible disturbance'' for casual collecting means little or no change to the surface of the land, and minimal or no effect to natural and cultural resources. This proposed definition would specify that in no circumstance may the surface disturbance exceed 1 square yard (3 feet by 3 feet) per individual collector; that in cases of multiple collectors each square yard of surface disturbance must be separated by at least 10 feet; and that all areas of surface disturbance must be backfilled with the material that was removed in order to render the disturbance substantially unnoticeable to the casual observer. The reason for using the ''1 square yard'' maximum is that this would be similar to longstanding BLM practice, and such consistency is encouraged by PRPA. In the context of compliance with the National Environmental Policy Act (NEPA) in the issuance of research permits for BLM, for instance, a proposal to engage in surface disturbance of anything larger than 1 square meter is not usually subject to categorical exclusion but is subject to further analysis under NEPA. The fossil-collecting community should, therefore, already be familiar with this type of threshold. For purposes of managing ''negligible disturbance,'' 1 square yard is considered to be approximately equal to 1 square meter.

The proposed definition would also specify that collecting areas need to be separated by at least 10 feet where there is surface disturbance. The separation would reduce cumulative effects to other resources. Where there is no surface disturbance, there is no need to separate collecting areas.

Proposed § 49.810(a)(4) would address the uses to which casually collected resources can be put. Casually collected resources may be used only for noncommercial personal use, which means a use other than purchase, sale, financial gain, or research. The restriction on any commercial use of casually collected resources is not new. For instance, rules of conduct applicable to BLM-managed public lands currently allow casual collecting of paleontological resources only for ''noncommercial purposes'' (43 CFR 8365.1–5(b)).

Proposed § 49.810(a)(5) would define the kinds of tools that may be used to casually collect these resources. These tools must be small, such as a geologic hammer, trowel, or sieve; they cannot use or be operated by a motor, engine, or other mechanized power source; and they must be light and small enough to be hand-carried by one person. A tool that exceeds this definition cannot be used to casually collect these resources.

Proposed § 49.810(b) would enable the authorized officer to establish limitations on casual collecting, in addition to the limitations already contained in the proposed rule. Examples of additional limitations include reducing the maximum weight for ''reasonable amount,'' decreasing the threshold for negligible disturbance, limiting depth of allowable disturbance, limiting specific tools that may be used, defining what is common in a specific area, establishing time or duration limits for collecting, establishing limits to avoid cumulative effects, and establishing parameters for safety.

Proposed § 49.810(c) would clarify that casual collecting is not allowed when any of the parameters that restrict casual collecting (reasonable amount, common invertebrate and plant paleontological resources, personal noncommercial use, negligible disturbance and non-powered hand tools) is exceeded or does not apply. Casual collecting is a limited exception to the overarching permit requirement of PRPA, and is allowed under the presumption that the ''commonness'' of these resources, in combination with limitations on amount, surface disturbance, tools, and eventual use of the collected resources, contributes to the underlying objective of protecting paleontological resources on federal lands. Proposed § 49.810(c) also clarifies that casual collecting in excess of the specified limitations is prohibited and subject to civil and criminal penalties.

IV. Proposed Conforming Amendment to 43 CFR part 8360—Visitor Services; Sections 8360.0–3, Authority, and 8365.1–5, Property and Resources

PRPA requires the BLM to allow the casual collecting of common invertebrate and plant paleontological resources, which is consistent with existing BLM policy. However, this rule would amend the text at existing 43 CFR 8365.1–5 to conform to the language used by PRPA.

The authority citations for 43 CFR part 8360 and the list of authorities at § 8360.0–3 would each be amended to add PRPA (16 U.S.C. 470aaa *et seq.*). PRPA introduces the term ''casual collecting'' to define the noncommercial collection of invertebrate and plant fossils, which was previously authorized by the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*). PRPA and the proposed regulations at part 49 use the term ''paleontological resources'' instead of the term ''fossils'' to describe resources that are managed under PRPA.

The current § 8365.1–5 would be amended to conform to the terms introduced by PRPA. The specific changes are:

- § 8365.1–5(b)(2) would be amended to remove the phrase ''common invertebrate and common plant fossils;''
- § 8365.1–5(b)(4) would be amended to remove ''and'' in order to maintain grammatical structure;
- § 8365.1–5(b)(5) would be amended to add ''and'' in order to maintain grammatical structure; and
- A proposed new § 8365.1–5(b)(6) would be added to include ''common invertebrate and plant paleontological resources'' on the list of things that may be collected from BLM public lands in reasonable amounts for noncommercial purposes. The paragraph also provides a reference to proposed part 49, which would authorize and provide rules for casual collecting.

V. Proposed Conforming Amendment to 50 CFR Part 27—Prohibited Acts, § 27.63, Search for and Removal of Other Valued Objects

PRPA states that a paleontological resource may not be collected from federal land without a permit issued under that authority. The proposed amendment at § 27.63 would add a paragraph that states that a permit is required in order to collect paleontological resources and would provide a reference to proposed part 49, which would authorize and provide rules for issuing permits under PPRA.

Proposed new § 27.63(c) would state that permits are required for paleontological studies on national wildlife refuges in accordance with the provisions at proposed 43 CFR part 49.

VI. 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 (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this proposed 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. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

This proposed rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on the cost-benefit and regulatory flexibility analyses found in the report titled ''Proposed Paleontological Resources Preservation Regulations, 43 CFR part 49: Economic Analysis In Support Of E.O. 12866 and Regulatory Flexibility Act Compliance,'' which can be viewed at *www.blm.gov/paleontology* by clicking on the link entitled ''Proposed Paleontological Resources Preservation Regulations, 43 CFR part 49: Economic Analysis In Support Of E.O. 12866 and Regulatory Flexibility Act Compliance.''

Small Business Regulatory Enforcement Fairness Act

This proposed 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 (UMRA)

This proposed rule does not impose an unfunded mandate on state, local, or tribal governments or the private sector of more than $100 million per year. This rule will not have a significant or unique effect on state, local, or tribal governments or the private sector. The rule addresses the management of paleontological resources from lands managed by BLM, Reclamation, FWS, and NPS, and imposes no requirements on other agencies or governments. A statement containing information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This proposed rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. This proposed rule is not a government action capable of interfering with constitutionally protected property rights. It would implement the new statutory authority for managing, preserving, and protecting paleontological resources on federal lands and is consistent with prior policies, procedures, and practices for the collection and curation of paleontological resources on federal land. Private property is not affected. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, this proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This rule addresses the management of paleontological resources on and from lands managed by the BLM, Reclamation, FWS, and NPS, and imposes no requirements on other agencies or governments. It does not have a substantial direct effect on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the levels of government. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This proposed rule complies with the requirements of Executive Order 12988. Specifically, 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 and Coordination With Indian Tribal Governments (Executive Order 13175 and Departmental Policy)

DOI 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. We have evaluated this proposed rule under DOI's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation is not required. This proposed rule applies to lands managed by BLM, Reclamation, FWS, and NPS. It does not apply to and has no direct effect on tribal trust lands or lands subject to a restriction on alienation imposed by the United States.

DOI is sending a letter to notify the 566 federally recognized Indian tribes that the proposed rulemaking is being published in the **Federal Register**. DOI invites responses to the notification letter.

Paperwork Reduction Act of 1995 (PRA)

This proposed rule contains a collection of information that has been submitted to OMB for approval under the PRA (44 U.S.C. 3501 *et seq.*). DOI and its bureaus may not conduct or sponsor, and no one is required to respond to, a collection of information unless it displays a currently valid OMB control number.

OMB has reviewed and approved the information collection requirements associated with the NPS' application and reports for paleontological permits (OMB Control Number 1024–0236).

DOI proposes to collect the following information associated with paleontological permits for work on lands administered by the BLM, Reclamation, and FWS:

Permit application (§ 49.65). Permit applicants proposing to work in areas administered by BLM, Reclamation, or FWS must provide the information requested by DI Form 9002 (*Paleontological Resource Use Permit Application*). Such information includes:

(1) Applicant's name, affiliation, and contact information.

(2) Current resume for the applicant and all other persons who will oversee fieldwork and other work.

(3) Description, estimated start and end dates of proposed work, and maps and other location information.

(4) Purpose and methodology of proposed work, including a detailed scope of work or research plan for the proposed activity, logistical information, methods that will be employed to explore for or remove the paleontological resources, proposed content and nature of any collection to be made under the permit.

(5) Bonding information.

(6) Information about the proposed repository.

(7) Information on the applicant's past performance on previous permits.

Change of personnel (§ 49.75(a)(2)). Permittee must report changes in the persons who are conducting activities under the permit, and submit the credentials of any new persons to the authorized officer for approval.

Locality information (§ 49.75(a)(1) & (7)). Permittee will record locality information on DI Form 9004 (*Paleontological Locality Form*), or in another format approved by the bureau in the permit that captures the same information.

Resource damage or theft (§ 49.75(a)(8)). Permittee must report suspected resource damage or theft of paleontological or other resources to the authorized officer as soon as possible, but not to exceed 48 hours after learning of such damage or theft.

Repository receipt (§ 49.75(a)(9) & (10)). Permittee must deposit the collection in the approved repository and provide the bureau with DI Form 9008 (*Repository Receipt for Collections (Paleontology)*), which includes a certification by the permittee that the collection was transferred to the repository and a certification by the approved repository's authorized official that the collection was received.

List and description of paleontological resources (§ 49.75(a)(11)). If the permittee has not transferred the collection to the approved repository by the due date of the annual report or other schedule approved for the permit, the permittee must provide the authorized officer a complete list and description of all paleontological resources collected and the current location of the paleontological resources.

Reports (§ 49.75(a)(15)). Permittees conducting activities on lands administered by BLM, Reclamation, or FWS must submit reports to the bureaus using DI Form 9005 (*Paleontological Permit Report Cover Sheet*), or DI Form 9006 (*Paleontology Consulting Report Summary Sheet*).

Amendments to permits (§ 49.80(a)). Permittees may request a modification to a permit. Modification requests will include permittee name, permit number, and the reason(s) for the modification request.

Objecting to a Notice of Violation (§ 49.515(a) & (b)). When a person receives a notice of violation, the person has 30 days from the date the notice was received to object by submitting to the authorized officer documentation to support the position that the person did not commit a violation or that the proposed penalty should be reduced or eliminated.

Responding to a civil penalty (§ 49.535(a)). A person may request a hearing on the authorized officer's final assessment of a civil penalty by filing a request for hearing via certified mail (return receipt requested or other verifiable delivery method) to the Departmental Cases Hearings Division, Office of Hearings and Appeals, Department of the Interior, 351 S. West Temple, Room 6.300, Salt Lake City, Utah 84101. The request for hearing must include the following information:

(1) The reasons for challenging the final assessment;

(2) The relief sought and the basis for the relief;

(3) A copy of the original notice of civil violation and proposed civil penalty assessment;

(4) A copy of any objection and supporting documentation filed under § 49.515(a);

(5) A copy of the final assessment of civil penalty; and

(6) A certificate of service acknowledging service of the request for hearing with the accompanying documentation on the Office of the Solicitor.

OMB Control No.: 1093–NEW.

Title: Application and Reports for Paleontological Permits, 43 CFR part 49.

Form Number(s): DI Forms 9002, 9004, 9005, 9006, and 9008.

Description of Respondents: Individuals; organizations; businesses (museums and universities); state, tribal, or local governments that collect paleontological resources or disturb paleontological sites on DOI lands.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Requirement	Total annual responses	Completion time per response (hours)	Total annual burden hours
Permit Application—DI Form 9002—§ 49.65; DI Form 9003—§ 49.75(a); DI Form 9007—§ 49.75(d)	440	4	1,760
Report Change of Personnel—§ 49.75(a)(2)	100	1	100
Locality Information—DI Form 9004—§ 49.75(a)(1) & (7)	300	1	300
Report Resource Damage or Theft –§ 49.75(a)(8)	50	1	50
Repository Receipt—DI Form 9008–§ 49.75(a)(9)&(10)	300	1	300
List and Description of Paleontological Resources—§ 49.75(a)(11)	100	1	100
Reports—DI Form 9005, Permit Report Cover Sheet—§ 49.75(a)(15)	374	5	1,870
Reports—DI Form 9006, Consulting Summary Report—§ 49.75(a)(15)	66	5	330
Request Amendment to Permit—§ 49.80(a)	200	1	200
Objecting to a Notice of Violation—§ 49.515(a)&(b)	10	10	100
Responding to a Civil Penalty—§ 49.535(a)	5	10	50
Totals	1,945		5,160

Estimated Nonhour Cost Burden: None.

Send comments specific to the information collection aspects of this proposed rule to the Desk Officer for the Department of the Interior with a copy to the Office of the Secretary Information Collection Clearance Officer, Department of the Interior. See the **DATES** and **ADDRESSES** sections for specific instructions.

National Environmental Policy Act

This proposed rule is anticipated to be categorically excluded from National Environmental Policy Act analysis under DOI categorical exclusion, 43 CFR 46.210(i), which covers ''Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively, or case-by-case.''

The categorical exclusion is appropriate and applicable for the

following reasons. Several of the provisions of this proposed rule are specifically administrative, financial, legal or procedural in nature, and therefore are subject to the first part of the categorical exclusion. For instance, the provisions for permit modification, suspension, revocation, or cancellation are all administrative or procedural in character, as are the rule's provisions establishing procedures to challenge any of these decisions. Similarly, the proposed rule sets forth specifics of the administration of civil and criminal penalties associated with violation of the provisions of the rule and of PRPA.

Both the establishment of the permit system, and future decisions to close lands to casual collecting (and, conversely, to open lands to casual collecting where that use is not already authorized) are subject to the second part of the categorical exclusion. Issuance of a permit (whether programmatic or individual in scope) for the collection of paleontological resources itself requires agency compliance with NEPA. Moreover, a permit must contain permit conditions, supported by appropriate NEPA analysis, that ensure the underlying project or action will continue to meet regulatory requirements throughout the entire duration of the permit. Likewise, any decision to close or open lands to casual collecting also requires agency compliance with NEPA and may contain conditions, supported by appropriate NEPA analysis, that ensure the appropriate management of these resources. Because the environmental effects of this proposed rule are too speculative to lend themselves to meaningful analysis, and the environmental consequences of any of these decisions will be analyzed in detail at the time the permit application or proposed opening or closing to casual collecting is evaluated and before a decision is made, the rule is subject to the second part of DOI categorical exclusion, 43 CFR 46.210(i).

Pursuant to 43 CFR 46.205(c), DOI has reviewed its reliance upon this categorical exclusion against the list of extraordinary circumstances, at 43 CFR 46.215, and has found that none applies to this rule. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required for this rulemaking.

Even though neither an EA nor an EIS must be prepared for this rule, the BLM has elected to prepare an EA to inform decision makers regarding the possible effects of two specific provisions as applied to the public lands BLM manages, as allowed under DOI's regulations implementing NEPA, 43 CFR 46.300(b)(1). BLM-administered lands are open to casual collection of paleontological resources unless specifically closed by a site-specific decision. As such, casual collection has been and will continue to occur on certain public lands.

PRPA provides specific authority and limits under which this activity can take place. In particular, PRPA allows for ''casual collecting,'' which is defined as ''the collecting of a reasonable amount of common invertebrates and plant paleontological resources for non-commercial personal use, either by surface collection or the use of non-powered hand tools resulting in only negligible disturbance to the Earth's surface and other resources'' (Pub. L. 111–11, section 6301(1), 123 Stat. 1172), and specifies that the Secretary of the Interior is to determine how these terms are to be defined. The rule's proposed definitions for ''negligible disturbance'' and ''reasonable amount'' describe the conditions limiting any casual collection activities on certain public lands managed by the BLM. The BLM is preparing an EA for these proposed definitions, which will immediately apply to casual collection on BLM public lands when this rule is finalized. The EA is under development and may be found at *www.blm.gov/paleontology.* The BLM welcomes input from the public on the EA, which may be revised in response to public input as well as further agency review. It is expected that analysis will be qualitative and descriptive in character, and consist largely of presenting the possible negative consequences that might result from not defining these terms carefully, as well as describing the considerations that informed the proposed definitions and the alternatives considered.

Effects on the Energy Supply (Executive Order 13211)

This proposed rule is not a significant energy action under the definition in Executive Order 13211. DOI has determined that this proposed rule will not have substantial direct effects on energy supply, distribution, or use, including a shortfall in supply or price increase. The rule has no bearing on energy development and will have no effect on the volume or consumption of energy supplies. A Statement of Energy Effects is not required.

Clarity of This Regulation

DOI is required by Executive Orders 12866 (section 1(b)(12)), 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 we publish 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 believe the DOI has not met these requirements, send comments by one of the methods listed in the **ADDRESSES** section. To better help us to revise the rule, please make comments as specific as possible. For example, tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you believe lists or tables would be useful, etc.

Drafting Information

This proposed rule reflects the efforts of staff in BLM, Reclamation, FWS, and NPS.

Public Participation

DOI, whenever practicable, affords 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. All comments must be received by midnight of the close of the comment period. We will not accept bulk comments in any format (hard copy or electronic) submitted on behalf of others.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, please know that we may make your entire comment—including your personal identifying information—publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

List of Subjects

43 CFR Part 49

Casual collecting, Civil penalties, Collecting, Commercial value, Confidentiality, Criminal penalties, Curation, Museums, Natural resources, Paleontological resources, Paleontology, Permits, Prohibited acts, Prohibitions, Public awareness, Public education, Recreation, Reporting and record keeping requirements, Repository, Research, Scientific principles, Scientific value.

43 CFR Part 8360

Penalties, Public lands, Recreation activities, Recreation and recreation areas.

50 CFR Part 27

Wildlife refuges.

For reasons stated in the preamble, the Department of the Interior proposes to amend title 43 of the CFR by adding part 49 and amending part 8360 and to amend part 27 of title 50, as set forth below:

Title 43: Public Lands: Interior

Subtitle A—Office of the Secretary of the Interior

■ 1. Add part 49 to title 43 to read as follows:

PART 49—PALEONTOLOGICAL RESOURCES PRESERVATION

Subpart A—Managing, Protecting, and Preserving Paleontological Resources

Sec.
49.1 What does this part do?
49.5 What terms are used in this part?
49.10 Does this part affect existing authorities?
49.15 When does this part not apply?
49.20 Does this part create new rights or entitlements?
49.25 What information concerning the nature and specific location of paleontological resources is confidential?
49.30 How will the bureaus conduct inventory, monitoring, and preservation activities?
49.35 How will the bureaus foster public education and awareness?
49.40 When may the bureaus restrict access to an area?

Subpart B—Paleontological Resources Permitting—Requirements, Modifications, and Appeals

49.50 When is a permit required on federal land?
49.55 Who can receive a permit?
49.60 What criteria must a permit applicant meet?
49.65 Where must a permit application be filed and what information must it include?
49.70 How will a bureau make a decision about a permit application?
49.75 What terms and conditions will a permit contain?
49.80 When and how may a permit be modified, suspended, revoked, or cancelled?
49.85 Can a permit-related decision be appealed?
49.90 What is the process for appealing a permit-related decision?
49.95 Has OMB approved the information collection provisions of this part?

Subpart C—Management of Paleontological Resource Collections

49.200 Where are collections deposited?
49.205 How will bureaus approve a repository for a collection made under this part?
49.210 What is the process for depositing the collection at the approved repository?
49.215 What terms and conditions must the agreement between the bureau and approved repository contain?
49.220 What are the standards for managing the collections?

Subpart D—Prohibited Acts

49.300 What acts are prohibited?

Subpart E—Criminal Penalties

49.400 What criminal penalties apply to violations of this part?

Subpart F—Civil Penalties

49.500 When can the authorized officer assess a civil penalty?
49.505 How does the authorized officer serve a notice of violation?
49.510 What is included in the notice of violation?
49.515 How is an objection to a notice of violation and proposed civil penalty made and resolved?
49.520 When will the authorized officer issue a final assessment of civil penalty?
49.525 How will the authorized officer calculate the amount of a proposed and final assessment of civil penalty?
49.530 How will the authorized officer issue the final assessment of civil penalty?
49.535 What are the options and timeframe to respond to the final assessment of civil penalty?
49.540 What procedures govern the DCHD hearing process initiated by a request for hearing on the final assessment?
49.545 What will be included in the administrative law judge's decision?
49.550 How can the administrative law judge's decision be appealed?
49.555 What procedures govern an appeal of an administrative law judge's decision to the OHA Director?
49.560 When must the civil penalty be paid?
49.565 When may a person assessed a civil penalty seek judicial review?
49.570 What happens if a civil penalty is not paid on time?
49.575 How will collected civil penalties be used?

Subpart G—Determining Values and the Costs of Response, Restoration, and Repair

49.600 What is scientific value?
49.605 What is commercial value?
49.610 What is the cost of response, restoration, and repair?

Subpart H—Forfeiture and Rewards

49.700 Will a violation lead to forfeiture of a paleontological resource?
49.705 What rewards may bureaus pay to those who assisted in enforcing this part?

Subpart I—Casual Collection of Common Invertebrate or Plant Paleontological Resources on Bureau of Land Management and Bureau of Reclamation Administered Lands

49.800 Is casual collecting allowed on lands administered by NPS or FWS?
49.805 Is casual collecting allowed on lands administered by BLM or Reclamation?
49.810 What is casual collecting?

Authority: 16 U.S.C. 470aaa–aaa–11.

Subpart A—Managing, Protecting, and Preserving Paleontological Resources

§ 49.1 What does this part do?

This part:

(a) Directs the Bureau of Land Management (BLM), Bureau of Reclamation (Reclamation), U.S. Fish and Wildlife Service (FWS), and National Park Service (NPS) (collectively referred to as ''the bureaus'') to manage, protect, and preserve paleontological resources on federal land using scientific principles and expertise;

(b) Coordinates paleontological resources management among the bureaus;

(c) Promotes public awareness; provides for collection under permit; clarifies that paleontological resources cannot be collected from federal land for sale or purchase; establishes civil and criminal penalties; sets curation standards; and

(d) Authorizes casual collecting of common invertebrate and plant fossils from certain BLM-administered land and certain Reclamation-administered land.

§ 49.5 What terms are used in this part?

The terms used in this part have the following definitions.

Act means title VI, subtitle D of the Omnibus Public Land Management Act on Paleontological Resources Preservation (16 U.S.C. 470aaa–470aaa–11).

Ad Hoc Board means an Ad Hoc Board of Appeals appointed by the Director, Office of Hearings and Appeals, Department of the Interior.

Approved repository means a federal or non-federal facility that provides curatorial services and that is approved by the authorized officer to receive collections made under this part.

Associated records means original records or copies thereof, regardless of format, that include but are not limited to:

(1) Primary records relating to identification, evaluation, documentation, study, preservation, context, or recovery of a paleontological resource;

(2) Public records including, but not limited to, land status records, bureau reports, publications, court documents, and agreements; and

(3) Administrative records and reports generated during the permitting process that pertain to survey, excavation, or study of the paleontological resource.

Authorized officer means the bureau director or employee to whom the Secretary of the Interior has delegated authority to take action under the Act. Delegation will follow applicable Department and bureau procedures.

Bureau means Bureau of Land Management (BLM), Bureau of Reclamation (Reclamation), U.S. Fish and Wildlife Service (FWS), or National Park Service (NPS).

Collection means paleontological resources removed from geological context or taken from federal land, and associated records or replicas.

Consumptive use means the alteration or destruction of a paleontological specimen or portion of a specimen for scientific research.

Cost of response, restoration, and repair means the costs to respond to a violation of the provisions of this part or a permit issued under this part and the costs of restoration and repair of the paleontological resources or paleontological sites damaged as a result of the violation. Those costs are described in greater detail in § 49.610.

Curatorial services means managing and preserving a museum collection over the long term according to Department and bureau museum and archival standards and practices.

Day means a calendar day.

DCHD means the Departmental Cases Hearings Division, Office of Hearings and Appeals, Department of the Interior.

Department or DOI means the Department of the Interior.

Federal land means land controlled or administered by the Secretary of the Interior, except for Indian land.

Fossilized means preserved by natural processes, such as burial in accumulated sediments, preservation in ice or amber, or replacement by minerals, which may or may not alter the original organic content.

Indian land means land of federally-recognized Indian tribes or Indian individuals which is either held in trust by the United States or subject to a restriction against alienation imposed by the United States.

Nature means physical features, identifications, or attributes of the paleontological resource.

OHA means the Office of Hearings and Appeals, DOI.

OHA Director means the Director, Office of Hearings and Appeals, DOI.

Paleontological resource means any fossilized remains, traces, or imprints of organisms preserved in or on the Earth's crust, except for:

(1) Those that are found in an archaeological context and are an archaeological resource as defined in section 3(1) of the Archaeological Resources Protection Act of 1979 (16 U.S.C. 470bb(1)); or

(2) ''Cultural items,'' as defined in section 2 of the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001 *et seq.*); or

(3) Resources determined in writing by the authorized officer to lack paleontological interest or not provide information about history of life on earth, based on scientific and other management considerations.

Paleontological site means a locality, location, or area where a paleontological resource is found; the site can be relatively small or large.

Specific location means any description or depiction of a place in such detail that it would allow a person to find a paleontological resource or the site from which it was collected.

State means one of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, or any other territory or possession of the United States.

Working collections means paleontological resource collections that are not intended for long-term preservation and care as museum collections.

§ 49.10 Does this part affect existing authorities?

No. This part preserves the authority of the Secretary of the Interior and the bureaus under this and other laws and regulations to manage, protect, and preserve paleontological resources on federal land.

§ 49.15 When does this part not apply?

(a) The regulations in this part do not invalidate, modify, or impose additional restrictions or permitting requirements on mineral, reclamation, or related multiple use activities for which authorization exists or permits are issued under the general mining, mineral leasing, geothermal leasing, or mineral materials disposal laws.

(b) The regulations in this part do not apply to Indian land.

(c) The regulations in this part do not apply to any land other than federal land as defined in this part, or resources other than paleontological resources as defined in this part.

§ 49.20 Does this part create new rights or entitlements?

(a) This part does not create any right, privilege, benefit, or entitlement for any person who is not an officer or employee of the United States acting in that capacity.

(b) Only an officer or employee of the United States acting in that capacity has standing to file a civil action in a court of the United States to enforce this part.

§ 49.25 What information concerning the nature and specific location of paleontological resources is confidential?

(a) In keeping with section 6309 of the Act, information concerning the nature and specific location of a paleontological resource is exempt from disclosure under the Freedom of Information Act and any other law unless the authorized officer determines that disclosure would:

(1) Further the purposes of the Act;

(2) Not create risk of harm to or theft or destruction of the resource or site containing the resource; and

(3) Be in accordance with other applicable laws.

(b) If the authorized officer determines that a proposed disclosure would meet the requirements of paragraphs (a)(1)–(a)(3) of this section, then the authorized officer will, prior to disclosing the information, enter into a written agreement with the party seeking the disclosure. Such agreement will provide stipulations focused on ensuring that the recipient of the disclosure does not publicly distribute or otherwise release, disclose, or share the information.

(c) No disclosure complying with paragraph (b) of this section will be considered an official public disclosure for purposes of the Freedom of Information Act.

§ 49.30 How will the bureaus conduct inventory, monitoring, and preservation activities?

(a) The bureaus will develop plans and procedures for the inventory and monitoring of paleontological resources on and from federal land in accordance with applicable laws and regulations.

(b) The bureaus will manage, protect, and preserve paleontological resources on and from federal land using scientific principles and expertise.

(c) Activities under paragraphs (a) and (b) of this section will be coordinated with other agencies, non-federal partners, the scientific community, and the general public where appropriate and practicable.

§ 49.35 How will the bureaus foster public education and awareness?

The bureaus will establish a program to increase public awareness about the significance of paleontological resources on or from federal land. This effort will be coordinated with other agencies, non-federal partners, the scientific community, and the general public where appropriate and practicable.

§ 49.40 When may the bureaus restrict access to an area?

(a) The authorized officer may restrict access to an area or close areas to collection of paleontological resources to protect paleontological or other resources or to provide for public safety.

(b) The regulations in this part do not preclude the use of other authorities that provide for area restrictions or closures on federal land.

Subpart B—PALEONTOLOGICAL RESOURCES PERMITTING—REQUIREMENTS, MODIFICATIONS, AND APPEALS

§ 49.50 When is a permit required on federal land?

(a) A permit is required for any person to collect paleontological resources or disturb paleontological sites, except for casual collecting on certain lands managed by the BLM or Reclamation, which is defined and addressed in subpart I of this part.

(b) A permit may be required by a bureau for activities that do not involve collection or disturbance.

(c) A permit is required for Federal Government personnel to collect paleontological resources or disturb paleontological sites unless the bureau authorizes the action by programmatic or other means.

§ 49.55 Who can receive a permit?

Applicants who demonstrate that they meet the qualification requirements described in § 49.60, who provide a complete application as described in § 49.65, and whose proposed activity meets the issuance criteria described in § 49.70 may receive a permit.

§ 49.60 What criteria must a permit applicant meet?

(a) Permit applicant qualification requirements include:

(1) A graduate degree from an accredited institution in paleontology or related field of study with a major emphasis in paleontology or equivalent academic training to undertake the proposed activity;

(2) Experience in collecting, analyzing, summarizing, and reporting paleontological data, and preparing collections for long-term care;

(3) Experience in planning, equipping, staffing, organizing, and supervising field crews on projects similar to the type, nature, and scope of work proposed in the application; and

(4) Other expertise, knowledge, or experience required by the bureau in policies or procedures.

(b) Past performance by the applicant will also be considered. Past performance includes compliance with previous permits, relevant civil or criminal violations, or current indictments or charges.

§ 49.65 Where must a permit application be filed and what information must it include?

(a) A permit applicant must submit an application to the bureau that administers the federal land where the proposed activity would be conducted. It is the permit applicant's responsibility to determine which bureau has jurisdiction, use that bureau's permit application form and process, and respond to that bureau's requests for information in a timely manner.

(b) A permit applicant proposing to work in areas administered by BLM, Reclamation, or FWS must provide the information requested by DI Form 9002 (*Paleontological Resource Use Permit Application*). A permit applicant proposing to work in areas administered by NPS must provide the information requested by the NPS's Research Permit and Reporting System. Such information, for purpose of both DI Form 9002 and the NPS System, includes:

(1) The applicant's name, affiliation, and contact information.

(2) A current resume for the applicant and all other persons who oversee work under the permit, and any additional information demonstrating that the applicant possesses the qualifications required by § 49.60.

(3) A description, estimated start and end dates, and maps and other location information for the proposed work.

(4) Purpose and methodology of proposed work, including a detailed scope of work or research plan for the proposed activity, logistical information, methods that will be employed to explore for or remove the paleontological resources, proposed content and nature of any collection to be made under the permit, collection management processes, timetable for transfer to the proposed repository, and any additional information that will help the authorized officer identify the extent, nature, and impacts of the proposal.

(5) Bonding information, if required by the bureau.

(6) Information about the proposed repository for any collection that would be made under the permit, including:

(i) Name, location, and contact information for the proposed repository;

(ii) Written verification from the proposed repository confirming that it will agree to receive the collection; and

(iii) Names of organizations responsible for costs of curatorial services.

(7) Information on the applicant's past performance on previous permits.

(c) Because of the span of activities covered by paleontological permits and the different management needs and resources of each bureau, applicants may not be required to provide all of the information listed in paragraph (b) of this section. Each bureau will have the discretion to ask for less information.

§ 49.70 How will a bureau make a decision about a permit application?

(a) The authorized officer will assess whether the permit application complies with other applicable authorities.

(b) The authorized officer may issue a permit upon determining that:

(1) The applicant possesses the qualifications required by § 49.60;

(2) The permitted activity and any collection that would be made under the proposed permit would further paleontological knowledge, public education, or management of paleontological resources;

(3) The permitted activity would be consistent with the purpose and management objectives defined for the federal land; and

(4) The permitted activity would be conducted in a manner that would avoid or reduce adverse effects to significant natural or cultural resources.

(c) The authorized officer will work with the permit applicant and proposed repository to decide whether to approve the proposed repository, based on the criteria described in § 49.205(a), for the collection that would be made under the permit.

§ 49.75 What terms and conditions will a permit contain?

(a) The authorized officer will use DI Form 9003 (*Paleontological Resource Use Permit*) when issuing permits for activities on lands administered by BLM, Reclamation, and FWS. The authorized officer will use the NPS Research Permit and Reporting System when issuing a permit for activities on lands administered by NPS. Permit terms and conditions will include but are not limited to:

(1) Permittee must not release, disclose, or share information about the specific location of paleontological resources without the prior written permission of the authorized officer.

(2) Permittee must report in writing to the authorized officer any change in the persons who are conducting activities under the permit, and submit the credentials of any new persons for approval.

(3) Permittee must protect paleontological sites and associated resources from harm resulting from the work under the permit, and is responsible for the actions of all persons working under the permit.

(4) Permittee, or a designee approved by the authorized officer and named on the permit, must be on site at all times when fieldwork is in progress and have a copy of the signed permit on hand.

(5) Permittee must comply with all vehicle or access restrictions, safety or environmental restrictions, local safety conditions or restrictions, and applicable federal, state, and local laws.

(6) Permittee acknowledges that the geographic area within the scope of the permit may be subject to other uses, and will take steps to avoid or minimize potential conflicts with such uses.

(7) Permittee will record locality information on DI Form 9004 (*Paleontological Locality Form*), or in another format approved for use under the permit that captures the same information.

(8) Permittee must report suspected resource damage or theft of paleontological or other resources to the authorized officer as soon as possible, but not to exceed 48 hours after learning of such damage or theft.

(9) A copy of the permit must be kept with the collection during transport and shared with the approved repository.

(10) Permittee must deposit the collection in the approved repository and provide the bureau with DI Form 9008 (*Repository Receipt for Collections (Paleontology)),* which includes but is not limited to a certification by the permittee that the collection was transferred to the repository and a certification by the approved repository's authorized official that the collection was received.

(11) If the permittee has not transferred the collection to the approved repository by the due date of the annual report or other schedule approved for the permit, the permittee must provide the authorized officer a complete list and description of all paleontological resources collected and the current location of the paleontological resources.

(12) Permittee acknowledges that all paleontological resources collected under the permit will remain federal property, and that he or she will not sell, trade, exchange, or keep for personal use the paleontological resources collected under the permit.

(13) Permittee must acknowledge the permitting bureau in any report, publication, paper, news article, film, television program, or other media resulting from the work performed under the permit.

(14) Permittee is responsible for the costs, monetary and otherwise, of the permitted activity, including fieldwork, data analysis, report preparation, curation of the collection and its associated records consistent with subpart C of this part.

(15) Permittees conducting activities on lands administered by BLM, Reclamation, or FWS must submit reports to the bureaus using DI Form 9005 (*Paleontological Permit Report Cover Sheet*), or DI Form 9006 (*Paleontology Consulting Report Summary Sheet*). Permittees conducting activities on lands administered by NPS must submit reports to the NPS under the NPS Research Permit and Reporting System.

(16) Permittee must comply with timelines established by the permit.

(17) Permittee must conduct the work consistent with the permit.

(18) Permittee must not transfer the permit.

(b) A permittee must continue to comply with applicable terms and conditions in the event of permit expiration, suspension, cancellation, or revocation unless specified otherwise by the authorized officer.

(c) The authorized officer may include in the permit additional terms and conditions necessary to carry out the purposes of this part, including a bond where warranted.

(d) For activities approved on lands administered by BLM or Reclamation, the authorized officer may provide permittees with DI Form 9007 (*Paleontology Work Notice to Proceed*), which contains site-specific guidance and stipulations for the permittee. The Notice to Proceed is part of the permit.

(e) Persons who do not comply with the terms of a permit issued under this part may be subject to civil or criminal penalties.

§ 49.80 When and how may a permit be modified, suspended, revoked, or cancelled?

(a) *Modification.* The authorized officer may modify a permit at the permittee's request; or when resource, safety, or other administrative or management reasons make permit modification appropriate; or when there is a violation of a term or condition of a permit issued under this part.

(b) *Suspension.* The authorized officer may suspend for up to 45 days activities under the permit when resource, safety, or other administrative or management reasons make permit suspension appropriate, or when the permittee violates a term or condition of the permit. If the issue prompting suspension is not resolved within the 45-day period, the authorized officer may modify, revoke, or cancel the permit as appropriate to the specific circumstance.

(c) *Revocation.* The authorized officer may revoke a permit when the permittee violates a term or condition of a permit, is found to be ineligible for a permit, or when the permittee fails to take the actions necessary for ending a suspension. The authorized officer will revoke a permit immediately if any person working under the authority of the permit is convicted of a criminal offense or assessed a civil penalty under this part.

(d) *Cancellation.* The authorized officer may cancel a permit when the permittee requests cancellation, or when resource, safety, or other administrative or management reasons make permit cancellation appropriate. Cancellation of a permit does not imply fault on the part of the permittee.

(e) Notification of modification, suspension, revocation, or cancellation.

(1) The authorized officer will notify the permittee of the modification, suspension, revocation, or cancellation verbally or in writing. The authorized officer will, as soon as practicable, confirm a verbal notification with a written notification. A written notification will be served on the permittee by certified mail, return receipt requested, or another verifiable delivery method. The notification will explain the reason for the modification, suspension, revocation, or cancellation.

(2) In the case of a suspension, the written notification will also include the conditions or actions necessary for ending the suspension; the anticipated duration of the suspension or schedule for resolution of the conditions that led to the suspension; and a statement that the permit will be modified, revoked, or cancelled if the conditions that led to the suspension are not resolved.

(3) The notification will inform the permittee how to appeal the modification, revocation, suspension, or cancellation.

(f) Immediately effective. A modification, suspension, revocation, or cancellation is in full force and effective

immediately upon the permittee's receipt of the written notification of the modification, suspension, revocation, or cancellation.

§ 49.85 Can a permit-related decision be appealed?

Permit applicants and permittees may appeal the denial of a permit application, and the modification, suspension, revocation, or cancellation of an issued permit.

§ 49.90 What is the process for appealing a permit-related decision?

A permit-related decision may be appealed using processes defined by the issuing bureau.

(a) Permit-related decisions by BLM may be appealed under the process explained at 43 CFR part 4, subpart E.

(b) Permit-related decisions by FWS may be appealed under the process explained at 50 CFR 36.41(i).

(c) Permit-related decisions by Reclamation may be appealed under the process used for other types of scientific research and collecting permits issued by Reclamation, which will be specified in writing in the permit-related decision.

(d) Permit-related decisions by NPS may be appealed under the process used for other types of scientific research and collecting permits issued by NPS, which will be specified in writing in the permit-related decision.

§ 49.95 Has OMB approved the information collection provisions of this part?

BLM, Reclamation, NPS, and FWS use the information collected under this part to manage, protect, and preserve paleontological resources on and from federal land. The Office of Management and Budget (OMB) reviewed and approved the information collection requirements contained in this part and assigned OMB Control No. 1093–XXXX. OMB has approved the information collection requirements for NPS Research Permit and Reporting System, which includes paleontological permits, and assigned OMB Control No. 1024–0236. A federal agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. You may send comments on the information collection requirements to the Office of the Secretary, Departmental Information Collection Clearance Lead, Department of the Interior, 1849 C Street NW., Mailstop MIB–7056, Washington, DC 20240.

Subpart C—Management of Paleontological Resource Collections

§ 49.200 Where are collections deposited?

(a) A collection from federal land made under a permit issued under this part will be deposited in the repository approved by the authorized officer under § 49.205.

(b) The curation of paleontological resources collected from federal land before January 6, 2017 is governed by the terms and conditions of the original collection permit or agreement.

§ 49.205 How will bureaus approve a repository for a collection made under this part?

(a) During the permit application process under subpart B of this part, the authorized officer will decide whether or not to approve a repository for the deposit of the collection that will be made under the permit, based on whether the:

(1) Repository has facilities and staff that provide curatorial services as defined in this part;

(2) Repository has a scope of collections statement or similar policy document that identifies paleontological resources as part of the repository's acquisition policy;

(3) Repository has access to paleontological and curatorial staff trained and experienced in managing and preserving paleontological resource collections;

(4) Repository's past and current performance meets applicable Departmental standards;

(5) Deposit would meet the bureau's management goals for the collection; and

(6) Repository will not release specific location data to the public except as consistent with § 49.25 or as provided in an agreement between the repository and the bureau.

(b) When the authorized officer approves a repository for the collection, that repository will be listed in the approved permit, and will remain approved to curate the collection unless the authorized officer determines that any one of the considerations in paragraph (a) of this section is no longer met. In that case, the authorized officer will notify the repository in writing and provide a reasonable time for the repository to:

(1) Correct the deficiency;

(2) Move the collection to another approved repository; or

(3) Take other actions the authorized officer requests.

§ 49.210 What is the process for depositing the collection at the approved repository?

(a) The authorized officer will take the following actions before the collection is deposited at the approved repository:

(1) Work with the permittee and approved repository, using scientific principles and expertise, to ensure that the collection is complete and that the content of the collection will further paleontological knowledge, public education, or management of paleontological resources;

(2) Review any existing agreement between the bureau and the approved repository to determine if that agreement adequately addresses requirements that are specific to the collection; and

(3) Develop a new agreement, if an adequate agreement does not exist between the repository and the bureau.

(b) After the collection is deposited at the approved repository, the permittee or the repository will submit DI Form 9008 (*Repository Receipt for Collections (Paleontology)*), to the authorized officer. This form includes but is not limited to a certification by the permittee that the collection was deposited at the repository, and a certification by the approved repository's authorized official that the collection has been received.

§ 49.215 What terms and conditions must the agreement between the bureau and approved repository contain?

(a) Agreements between the bureau and approved repository will contain the following information as deemed appropriate by the authorized officer:

(1) Statement (updated as necessary) that identifies the collection or group of collections at the approved repository.

(2) Statement that asserts federal ownership of the collection.

(3) Statement of work to be performed by the approved repository.

(4) Statement of the responsibilities of the bureau and of the approved repository for the long-term care of the collection.

(5) Statement that collections are available for scientific and educational uses and that the specific location data may be shared consistent with § 49.25.

(6) Description of any special procedures or restrictions for access to controlled property, consumptive use, reproductions, or curatorial services, including loans.

(7) Statement describing the frequency, methods, and reporting process for inventories.

(8) Statement that all exhibits, publications, and studies of paleontological resources will

acknowledge the bureau that administers the collection.

(9) Statement that copies of any publications or reports resulting from study of the collection will be made available to the bureau.

(10) Statement describing how collection management records will be made available to the bureau that administers the collection.

(11) Statement that employees of the repository will take no actions whereby any of the collection shall or may be encumbered, seized, taken, sold, attached, lost, stolen, destroyed or damaged.

(12) Effective term of the agreement and procedures for modification, cancellation, suspension, extension, and termination of the agreement, including costs.

(13) Additional terms and conditions as needed to manage the collection.

(b) The agreement must be signed by an authorized representative of the approved repository and the authorized officer.

§ 49.220 What are the standards for managing the collections?

(a) Each approved repository must:

(1) Provide curatorial services consistent with § 49.5, and make the collections available for scientific research, public education, and management uses that further the Act, subject to § 49.25;

(2) Ensure that use of the collections is consistent with Departmental and bureau museum management standards and the terms of the agreement between the bureau and the approved repository;

(3) Obtain approval of the authorized officer on a case-by-case basis before conducting or allowing reproduction or consumptive use of part or all of the collection, unless another procedure for obtaining such approval is defined in the agreement between the bureau and the approved repository;

(4) Obtain approval of the authorized officer and follow Departmental and bureau policy when moving part or all of the collection from museum to working collections; and

(5) Conduct inventories consistent with Departmental and bureau museum management standards, and report the results to the bureau.

(b) The approved repository may charge reasonable fees, consistent with applicable law, to persons who use, or institutions that borrow, part or all of a collection. Fees may cover costs for handling, packing, shipping, and insuring the collection, photocopying associated records, and other costs associated with that use.

Subpart D—Prohibited Acts

§ 49.300 What acts are prohibited?

A person may not:

(a) Excavate, remove, damage, or otherwise alter or deface or attempt to excavate, remove, damage, or otherwise alter or deface any paleontological resource located on federal land unless this activity is conducted in accordance with the Act and this part.

(b) Exchange, transport, export, receive, or offer to exchange, transport, export, or receive any paleontological resource if the person knew or should have known such resource to have been excavated or removed from federal land in violation of any provision, rule, regulation, law, ordinance, or permit in effect under federal law, including the Act and this part.

(c) Sell or purchase or offer to sell or purchase any paleontological resource if the person knew or should have known such resource to have been excavated, removed, sold, purchased, exchanged, transported, or received from federal land.

(d) Make or submit any false record, account, or label for, or any false identification of, any paleontological resource excavated or removed from federal land.

Subpart E—Criminal Penalties

§ 49.400 What criminal penalties apply to violations of this part?

(a) The penalties in this section do not apply with respect to paleontological resources in the lawful possession of a person on or before March 30, 2009.

(b) Anyone who knowingly violates or counsels, procures, solicits, or employs another person to commit a prohibited act identified in subpart D of this part will, upon conviction, be assessed:

(1) Fines in accordance with 18 U.S.C., or imprisonment of up to 5 years, or both, if the sum of the commercial and scientific value of the paleontological resources involved and the cost of response, restoration, and repair of the resources and sites involved is more than $500; or

(2) Fines in accordance with 18 U.S.C., or imprisonment of up to 2 years, or both, if the sum of the commercial and scientific value of the paleontological resources involved and the cost of response, restoration, and repair of the resources and sites involved is $500 or less.

(c) Commercial and scientific values and the cost of response, restoration, and repair are determined under subpart G of this part.

(d) In the case of a second or subsequent violation by the same person, the amount of the penalties assessed under this subpart may be doubled.

(e) To the extent that a prohibited act under this subpart involves a violation of other applicable law, the violator may be subject to other criminal penalties.

Subpart F—Civil Penalties

§ 49.500 When can the authorized officer assess a civil penalty?

(a) The authorized officer may assess a civil penalty upon any person who violates the provisions of this part or a permit issued under this part, in accordance with the process explained in this subpart.

(b) For purposes of this subpart, each violation is considered a separate offense.

§ 49.505 How does the authorized officer serve a notice of violation?

The authorized officer may serve a notice of violation in person, by certified mail, return receipt requested, or other verifiable delivery method upon a person that the authorized officer believes has committed a violation of this part.

§ 49.510 What is included in the notice of violation?

A notice of violation will include:

(a) A concise statement of the facts believed to show a violation has occurred;

(b) A citation of the provisions of this part or a permit issued under this part alleged to have been violated;

(c) The amount of civil penalty proposed;

(d) Notification of the right to await the final assessment of civil penalty or to object to the notice of violation and proposed civil penalty, and the right to file a request for hearing of the final assessment of civil penalty. The notice shall also inform the person of the right to seek judicial review upon the issuance of the final administrative order under this subpart; and

(e) The name and contact information of the authorized officer who is serving the notice of violation.

§ 49.515 How is an objection to a notice of violation and proposed civil penalty made and resolved?

(a) *Filing Objection.* A person served with a notice of violation and proposed civil penalty may file a written objection with the authorized officer within 30 days of the date the notice was received.

(b) *Content of Objection.* The objection must:

(1) Clearly and concisely state the reasons why the person believes that the person did not commit a violation and/

or that the proposed civil penalty should be reduced or eliminated;

(2) Be accompanied by any documentation supporting the person's reasons for objecting; and

(3) Be signed by the person or the person's authorized representative.

(c) *Issuing Determination.* The authorized officer will issue a determination, served on the person by a verifiable delivery method, sustaining or denying the objection to the notice of violation and/or proposed civil penalty based on the information contained in the written objection or furnished to the authorized officer upon further request.

(d) *Content of Determination.* In the determination, the authorized officer will:

(1) Sustain the objection and revoke the notice of violation and proposed civil penalty, if the authorized officer determines that the information warrants a conclusion that no violation occurred;

(2) Deny the objection, if the authorized officer determines that the information warrants a conclusion that a violation occurred and that the proposed civil penalty is not too high; or

(3) Deny the objection in part and sustain it in part, if the authorized officer determines that the information warrants a conclusion that a violation has occurred, but the amount of the civil penalty too high.

§ 49.520 When will the authorized officer issue a final assessment of civil penalty?

The authorized officer will issue a final assessment of civil penalty:

(a) If the person served with a notice of violation and proposed civil penalty does not file a timely objection; or

(b) If the person does file a timely objection that is denied in whole or in part under § 49.515.

§ 49.525 How will the authorized officer calculate the amount of a proposed and final assessment of civil penalty?

(a) The authorized officer will determine the amount of the civil penalty by taking into account:

(1) The scientific or commercial value, whichever is greater as determined by the authorized officer, of the paleontological resource involved;

(2) The cost of response, restoration, and repair of the paleontological resource and the paleontological site involved;

(3) Other factors that the authorized officer considers relevant, such as prior violations or warnings or evidence of malicious intent;

(4) Information provided under § 49.515 or furnished to the authorized officer upon his or her request; and

(5) Mitigating factors, which may include return of paleontological resources and whether the person will provide information that may assist the bureau.

(b) Scientific and commercial values and the cost of response, restoration, and repair are determined under subpart G of this part.

(c) In the case of any subsequent violation by the same person, the authorized officer may calculate a penalty in accordance with paragraph (a) of this section and double it for that subsequent violation.

(d) The maximum penalty assessed under paragraph (c) of this section for any one violation may not exceed the sum of:

(1) Two times the cost of response, restoration, and repair of paleontological resources and paleontological site damage; plus

(2) Two times the scientific or commercial value, whichever is greater as determined by the authorized officer, of the paleontological resources and paleontological sites destroyed or not recovered.

(e) The authorized officer will use subpart G of this part to determine scientific or commercial values and the cost of response, restoration, and repair.

(f) The final assessment may be equal to, less than, or more than the proposed civil penalty.

§ 49.530 How will the authorized officer issue the final assessment of civil penalty?

(a) The authorized officer will serve the final assessment of civil penalty by certified mail, return receipt requested, or other verifiable delivery method.

(b) The final assessment of civil penalty will include:

(1) The facts and conclusions that are the bases for the authorized officer's determination that a violation occurred;

(2) The basis for the authorized officer's determination of the amount of civil penalty assessed;

(3) Notification of the rights to accept the final assessment of civil penalty or, alternatively, to file a request for hearing on the final assessment with a DCHD administrative law judge under § 49.535(a)(2).

(4) A statement that the civil penalty must be paid within 30 days of the date that the final assessment of civil penalty is received, unless the person served with the final assessment of civil penalty files a request for hearing in accordance with this subpart and the procedures specified in the notice.

§ 49.535 What are the options and timeframe to respond to the final assessment of civil penalty?

(a) *Response Options.* A person who receives a final assessment of civil penalty may, within 30 days of the date the assessment is received, do one of the following:

(1) Accept the final assessment, either in writing, by payment of the proposed penalty, or by failing to timely file a request for hearing under paragraph (a)(2) of this section; or

(2) File a request for a hearing on the final assessment before a DCHD administrative law judge via certified mail, return receipt requested, or other verifiable delivery method with the Departmental Cases Hearings Division, Office of Hearings and Appeals, Department of the Interior, 351 S. West Temple, Room 6.300, Salt Lake City, Utah 84101.

(b) *Content of Request for Hearing.* A request for hearing must:

(1) Be signed by the person who receives the final assessment of civil penalty or a representative qualified to represent that person under 43 CFR 1.3;

(2) Identify the final assessment of civil penalty being challenged;

(3) State clearly and concisely the reasons for challenging the final assessment, including the reasons why the person believes that he or she did not commit a violation and/or that the proposed civil penalty should be reduced or eliminated;

(4) State the relief sought and the basis for that relief;

(5) Be accompanied by the following documentation:

(i) A copy of the notice of violation and proposed civil penalty;

(ii) A copy of any objection and supporting documentation filed under § 49.515(a); and

(iii) A copy of the final assessment of civil penalty; and

(6) Contain a certificate acknowledging service of the request for hearing with the documentation listed in paragraph (b)(5) of this section on the Office of the Solicitor at the address identified in paragraph (c) of this section.

(c) *Service.* The person filing a request for hearing must simultaneously send a copy of the request and the accompanying documentation to the Office of the Solicitor, Department of the Interior, 1849 C Street NW., Washington, DC 20240.

(d) *Dismissal of Hearing Request.*

(1) If the request for hearing is not received by DCHD within 30 days of the date of receipt of the final assessment, the request for hearing will not be considered and the hearing will be dismissed.

(2) The request for hearing may be dismissed for failing to meet any of the requirements of paragraph (c) of this section.

(e) *Waiver of Hearing Right.* A person who accepts the final assessment under paragraph (a)(1) of this section waives the right to a hearing.

§ 49.540 What procedures govern the DCHD hearing process initiated by a request for hearing on the final assessment?

(a) Upon receipt of a request for hearing under § 49.535(a)(2), DCHD will assign an administrative law judge to preside over the hearing process and issue a decision. DCHD will promptly notify the parties of the assignment. Thereafter, all pleadings, papers, and other documents in the hearing process must be filed directly with that judge, with copies served on the other party.

(b) An attorney from the Office of the Solicitor, DOI, will represent the bureau. The attorney will enter his or her appearance on behalf of the bureau and file all motions and correspondence between the bureau and the person who filed the request for hearing. Subsequently, any service upon the bureau must be made to the attorney.

(c) To the extent not inconsistent with the provisions of this subpart, the rules in 43 CFR part 4, subparts A and B, and in 43 CFR 4.422 through 4.437 will apply to the hearing process under this subpart.

(d) The hearing will be conducted in accordance with 5 U.S.C. 554. The bureau will have the burden of proving by a preponderance of the evidence the fact of the violation and the basis for the amount of the civil penalty. Upon completion of the hearing and incorporation of the hearing transcript in the record, the administrative law judge will issue a written decision in accordance with § 49.545 and serve it on the parties.

§ 49.545 What will be included in the administrative law judge's decision?

(a) The administrative law judge's written decision will set forth:

(1) The findings of fact and conclusions of law;

(2) The reasons and bases for the findings; and

(3) An assessment of the penalty, if any.

(b) The amount of any penalty assessed will:

(1) Be determined in accordance with this subpart; and

(2) Not be limited by the amount assessed by the authorized officer under § 49.525 or by any offer of mitigation or remission previously made.

(c) The administrative law judge's decision will become effective 31 days from the date of the written decision unless a timely appeal of the decision is filed under § 49.550.

§ 49.550 How can the administrative law judge's decision be appealed?

(a) *Filing appeal.* Within 30 days of the date of the administrative law judge's decision, either party to the hearing process (the person who filed the request for hearing or the bureau) may appeal the administrative law judge's decision to the OHA Director by filing a notice of appeal via certified mail, return receipt requested, or other verifiable delivery method to the Director, Office of Hearings and Appeals, Department of the Interior, 801 North Quincy Street, Arlington, Virginia 22203.

(b) *Content of notice of appeal.* The notice of appeal must:

(1) Be signed by the person filing the appeal or a representative qualified to represent that person under 43 CFR 1.3;

(2) Identify the administrative law judge's decision being appealed, including the DCHD docket number;

(3) State clearly and concisely the reasons for challenging the decision, including:

(i) The reasons why the person believes that he or she did not commit a violation and/or that the proposed civil penalty should be reduced or eliminated; and

(ii) A concise but complete statement of the facts relied upon to challenge the decision;

(4) State the relief sought and the basis for that relief;

(5) Be accompanied by the following documentation:

(i) A copy of the notice of violation and proposed civil penalty;

(ii) A copy of the final assessment of civil penalty; and

(iii) A copy of the administrative law judge's decision; and

(6) Contain a certificate acknowledging service of the notice with the documentation listed in paragraph (b)(5) of this section on the other party to the hearing process at the address listed on the administrative law judge's decision.

(c) *Service.* The person filing a notice of appeal must simultaneously send a copy of the notice and the accompanying documentation to each of the following entities at the address listed on the administrative law judge's decision:

(1) The other party to the hearing process; and

(2) DCHD.

(d) *Dismissal of appeal.* If the notice of appeal is not received by the OHA Director within 30 days of the date of the administrative law judge's decision, the notice of appeal will not be considered and the appeal will be dismissed.

(e) *Stay of payment deadline.* If the administrative law judge's decision is appealed to the OHA Director, the deadline for payment of the penalty will be stayed pending resolution of the appeal.

§ 49.555 What procedures govern an appeal of an administrative law judge's decision to the OHA Director?

(a) Upon receipt of a notice of appeal filed under § 49.550(a), the OHA Director will appoint an Ad Hoc Board to consider the appeal and issue a decision thereon.

(b) To the extent not inconsistent with the provisions of this subpart, the rules in 43 CFR part 4, subparts A, B, and G, will apply to the appeal proceedings under § 49.550.

§ 49.560 When must the civil penalty be paid?

A person assessed a civil penalty has 30 days from the date of the final administrative decision in which to make full payment of the final assessment of the civil penalty, or agree to a payment schedule. For the purposes of this subpart, the final administrative decision is:

(a) The final assessment of civil penalty if the person served with the final assessment does not file a timely request for hearing under § 49.535(a)(2).

(b) The administrative law judge's decision on the request for hearing if a timely appeal to the OHA Director is not filed under § 49.550(a); or

(c) The decision of the Ad Hoc Board of Appeals appointed by the OHA Director if a timely appeal of the administrative law judge's decision was filed under § 49.550(a).

§ 49.565 When may a person assessed a civil penalty seek judicial review?

A person may file a petition for judicial review in the United States District Court for the District of Columbia or in the district where the violation occurred, within 30 days of the decision of the Ad Hoc Board of Appeals appointed by the OHA Director. For purposes of the Act and this part, that decision will be considered a final administrative order. The deadline for payment of the civil penalty will be stayed pending resolution of the judicial review.

§ 49.570 What happens if a civil penalty is not paid on time?

(a) If the civil penalty is not paid by the required deadlines, the United

States may take action to collect the penalty assessed plus interest, attorneys' fees, and collection costs.

(b) Failure to pay a civil penalty assessed under this subpart is a debt to the United States.

(c) Failure to pay a civil penalty assessed under this subpart may prevent a person from obtaining a future authorization for activities related to paleontological resources on federal land as well as receiving other future federal funding or assistance.

(d) By assessing a civil penalty under this subpart, the United States does not waive the right to pursue other legal or administrative remedies.

§ 49.575 How will collected civil penalties be used?

Civil penalties collected under this subpart are available without further appropriation to the bureau that administers the federal land or paleontological resources that were the subject of the violation, and may be used only to:

(a) Protect, restore, or repair the paleontological resources and sites that were the subject of the action, and to protect, monitor, and study the resources and sites;

(b) Provide educational materials to the public about paleontological resources, paleontological sites, or resource protection; or

(c) Pay rewards under subpart H of this part.

Subpart G—Determining Values and the Costs of Response, Restoration, and Repair

§ 49.600 What is scientific value?

The scientific value of a paleontological resource is the value of the scientific and educational information associated with the resource. It is determined by the authorized officer based upon the estimated costs of obtaining the scientific and educational information from the disturbed paleontological site if the prohibited act had not occurred. These costs may include, but are not limited to:

(a) Research design development;

(b) Fieldwork;

(c) Laboratory analysis;

(d) Curation;

(e) Reports or educational materials; and

(f) Lost visitor services or experience.

§ 49.605 What is commercial value?

The commercial value of a paleontological resource is the monetary value of that resource, and is determined by the authorized officer using comparable sales information, appraisals, market value, or other information for comparable resources. If there is no comparable sales information, appraisal, market value, or other information, the authorized officer will determine the commercial value of the paleontological resource using other methods such as scientific value or the cost of response, restoration, and repair.

§ 49.610 What is the cost of response, restoration, and repair?

The cost of response, restoration, and repair of a paleontological resource or paleontological site is determined by the authorized officer, and includes but is not limited to the costs of:

(a) Law enforcement investigations;

(b) Immediate stabilization;

(c) Longer term response, restoration, and repair, including but not limited to reconstructing or stabilizing the resource or site, salvaging the resource or site, erecting physical barriers or other protective devices or signs to protect the site, and monitoring the site;

(d) Fossil preparation, stabilization, and conservation;

(e) Storage and curation of the resources; and

(f) Reporting upon the above activities.

Subpart H—Forfeiture and Rewards

§ 49.700 Will a violation lead to forfeiture of a paleontological resource?

(a) A paleontological resource with respect to which a violation under this part occurred is stolen federal property and is subject to forfeiture.

(b) The bureau may either deposit forfeited resources into an approved repository, or transfer or assign administration of the forfeited resources to federal or non-federal institutions to be used for scientific or educational purposes.

§ 49.705 What rewards may bureaus pay to those who assisted in enforcing this part?

(a) The bureau may pay a reward to the person or persons furnishing information leading to a finding of civil violation or criminal conviction.

(b) The reward may be no more than half of the penalties collected. If several persons provide the information, the bureau may divide the reward among them.

(c) The funds for the reward may come from the penalties collected or from appropriated funds.

(d) An officer or employee of federal, state, or local government who furnishes information or renders service in the performance of official duties is not eligible for a reward under this section.

Subpart I—Casual Collection of Common Invertebrate or Plant Paleontological Resources on Bureau of Land Management and Bureau of Reclamation Administered Lands

§ 49.800 Is casual collecting allowed on lands administered by NPS or FWS?

Casual collecting of paleontological resources is not allowed on lands administered by NPS or FWS. On those lands, collecting any paleontological resource must be conducted in accordance with a permit as described in subpart B of this part.

§ 49.805 Is casual collecting allowed on lands administered by BLM or Reclamation?

(a) Casual collecting of common invertebrate or plant paleontological resources is allowed on lands administered by BLM in accordance with this subpart, except:

(1) On any BLM-administered land that is closed to casual collecting in accordance with this part, other statutes, executive orders, regulations, or land use plans; or

(2) On BLM-administered national monuments, national conservation areas, outstanding natural areas, forest reserves, or cooperative management and protection areas, except where allowed by other statutes, executive orders, regulations, or land use plans.

(b) Casual collecting of common invertebrate or plant paleontological resources is allowed on land administered by Reclamation only in locations where Reclamation has established a special use area for casual collecting using processes defined in 43 CFR part 423, *Public Conduct on Bureau of Reclamation Facilities, Lands, and Waterbodies.* Casual collecting is prohibited on Reclamation project land that is administered by NPS or FWS.

(c) Persons interested in casual collecting are responsible for learning which bureau manages the land where they would like to collect paleontological resources, learning if the land is open to casual collecting, learning what may be collected in an area, and obtaining information about the managing bureau's casual collecting procedures.

§ 49.810 What is casual collecting?

(a) Casual collecting means the collecting without a permit of a reasonable amount of common invertebrate or plant paleontological resources for non-commercial personal use, either by surface collection or the use of non-powered hand tools, resulting in only negligible disturbance to the Earth's surface or paleontological or other resources.

(1) *Common invertebrate or plant paleontological resources* are invertebrate or plant fossils that have been established as having ordinary occurrence and wide-spread distribution. Not all invertebrate or plant paleontological resources are common.

(2) *Reasonable amount* means a maximum of 25 pounds per day per person, not to exceed 100 pounds per year per person. Pooling of individuals' daily amounts to obtain pieces in excess of 25 pounds is not allowed.

(3) *Negligible disturbance* means little or no change to the surface of the land and minimal or no effect to natural and cultural resources, specifically:

(i) In no circumstance may the surface disturbance exceed 1 square yard (3 feet × 3 feet) per individual collector;

(ii) For multiple collectors, each square yard of surface disturbance must be separated by at least 10 feet;

(iii) All areas of surface disturbance must be backfilled with the material that was removed so as to render the disturbance substantially unnoticeable to the casual observer.

(4) *Non-commercial personal use* means a use other than for purchase, sale, financial gain, or research.

(5) *Non-powered hand tool* means a small tool, such as a geologic hammer, trowel, or sieve, that does not use or is not operated by a motor, engine, or other mechanized power source, and that can be hand-carried by one person.

(b) In order to preserve paleontological or other resources, or for other management reasons, the authorized officer may establish limitations on casual collecting, including but not limited to reducing the weight of common invertebrate or plant paleontological resources below the amount specified in this subpart; limiting the depth of disturbance; establishing site-specific dates or locations for collecting; or establishing what is common in a specific area.

(c) Collecting common invertebrate or plant paleontological resources inconsistent with any of the limitations in paragraphs (a) or (b) of this section is not casual collecting, and must be immediately discontinued.

(d) Collecting common invertebrate or plant paleontological resources inconsistent with this subpart is a prohibited act and may result in civil or criminal penalties.

Subtitle B—Regulations Relating to Public Lands

Subchapter A—General Management

PART 8360—VISITOR SERVICES

■ 2. Revise the authority citation for part 8360 to read as follows:

Authority: 16 U.S.C. 470aaa *et seq.,* 670 *et seq.,* 877 *et seq.,* 1241 *et seq.,* and 1281c; and 43 U.S.C. 315a and 1701 *et seq.*

■ 3. Revise § 8360.0–3 to read as follows:

§ 8365.0–3 Authority.

The regulations of this part are issued under the provisions of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), the Sikes Act (16 U.S.C. 670g), the Taylor Grazing Act (43 U.S.C. 315a), the Wild and Scenic Rivers Act (16 U.S.C. 1281c), the Act of September 18, 1960, as amended, (16 U.S.C. 877 *et seq.*), the National Trails System Act (16 U.S.C. 1241 *et seq.*), and the Paleontological Resources Preservation Act (16 U.S.C. 470aaa *et seq.*).

■ 4. Amend § 8365.1–5 by revising paragraphs (b)(2), (b)(4), and (b)(5) and adding paragraph (b)(6) to read as follows:

§ 8365.1–5 Property and resources.

* * * * *

(b) * * *

(2) Nonrenewable resources such as rocks, mineral specimens, and semiprecious gemstones;

* * * * *

(4) Mineral materials as provided under subpart 3604;

(5) Forest products for use in campfires on the public lands. Other collection of forest products shall be in accordance with the provisions of Group 5500 of this title; and

(6) Common invertebrate and plant paleontological resources as provided under subpart 49 of this title.

* * * * *

Title 50: Wildlife and Fisheries

PART 27—PROHIBITED ACTS

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

Authority: 5 U.S.C. 685, 752, 690d; 16 U.S.C. 460k, 460*l*–6d, 664, 668dd, 685, 690d, 715i, 715s, 725; 43 U.S.C. 315a.

■ 6. Amend § 27.63 by adding paragraph (c) to read as follows:

§ 27.63 Search for and removal of other valued objects.

* * * * *

(c) Permits are required for the collection of paleontological resources on national wildlife refuges in accordance with the provisions of 43 CFR part 49.

Elizabeth Klein,

Principal Deputy Assistant Secretary, Policy Management and Budget.

[FR Doc. 2016–29244 Filed 12–6–16; 8:45 am]

BILLING CODE 4333–15–P; 4310–84–P; 4312–52–P; 4332–90–P

Notices

Federal Register

Vol. 81, No. 235

Wednesday, December 7, 2016

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

Food Safety and Inspection Service

[Docket No. FSIS–2016–0042]

National Advisory Committee on Microbiological Criteria for Foods

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice soliciting nominations for membership on the National Advisory Committee on Microbiological Criteria for Foods.

SUMMARY: The U.S. Department of Agriculture (USDA) is soliciting nominations for membership on the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). There are 15 vacancies. Advisory Committee members serve a two-year term, renewable for two consecutive terms.

USDA is seeking nominees with scientific expertise in the fields of microbiology, epidemiology, food technology (food, clinical, and predictive), toxicology, risk assessment, infectious disease, biostatistics, and other related sciences. USDA is seeking nominations for NACMCF from persons in academia, industry, State governments, and the Federal Government, as well as all other interested persons with the required expertise. Please note that federally registered lobbyists cannot be considered for USDA advisory committee membership.

USDA is also seeking nominations for one individual affiliated with a consumer group to serve on the NACMCF. This member will serve as a representative member to provide a consumer viewpoint to the committee. This member will not be required to have a scientific background and will not be subject to a conflict of interest review.

Members can serve on only one USDA advisory committee at a time. All nominees will undergo a USDA background check.

With the exception of the consumer representative member, any member who is not a Federal government employee will be appointed to serve as a non-compensated special government employee (SGE). SGEs will be subject to appropriate conflict of interest statutes and standards of ethical conduct.

Nominations for membership on the NACMCF must be addressed to the Secretary of USDA and accompanied by a cover letter addressing the nomination, a resume or curriculum vitae, and a completed USDA Advisory Committee Membership Background Information form AD–755 available online at: *https://www.ocio.usda.gov/document/ad-755.* A person may self-nominate, or a nomination can be made on behalf of someone else. The resume or curriculum vitae must be limited to five one-sided pages and should include educational background, expertise, and a list of select publications, if available, that confirm the nominee's expertise for this work. For submissions received that are more than five one-sided pages in length, only the first five pages will be reviewed.

DATES: All materials must be received by January 6, 2017.

ADDRESSES: Nomination packages should be sent via email to *karen.thomas-sharp@fsis.usda.gov* and mailed to: Tom Vilsack, Secretary, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250, Attn: FSIS\Office of Public Health Science\National Advisory Committee on Microbiological Criteria for Foods (Karen Thomas-Sharp).

FOR FURTHER INFORMATION CONTACT: Ms. Karen Thomas-Sharp, Advisory Committee Specialist, by telephone at 202–690–6620 or by email *karen.thomas-sharp@fsis.usda.gov.*

The Food Safety and Inspection Service (FSIS) invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods: Federal eRulemaking Portal: This Web site (*http://www.regulations.gov/*) provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Follow the online instructions at that site for submitting comments. Mail, including CD–ROMS and hand or courier delivered items: Send to Docket Clerk, USDA, FSIS Docket Room, Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700 between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Instructions: All items submitted by mail or email must include the Agency name and docket number FSIS–2016–0042. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov/.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 8–164, Washington, DC 20250–3700 between 8:30 a.m. and 4:30 p.m., Monday through Friday. All comments submitted in response to this notice, as well as background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The NACMCF was established in March 1988, in response to a recommendation in a 1985 report of the National Academy of Sciences Committee on Food Protection, Subcommittee on Microbiological Criteria, ''An Evaluation of the Role of Microbiological Criteria for Foods.'' The current charter for the NACMCF and other information about the Committee are available to the public for viewing on the FSIS Web site at: *http://www.fsis.usda.gov/nacmcf.*

The Committee provides scientific advice and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services concerning the development of microbiological criteria by which the safety and wholesomeness of food can be assessed. For example, one of the most recent efforts of the Committee is to provide the best scientific information available on Shiga Toxin producing *E. coli,* including providing recommendations on optimal detection and identification methodologies.

Appointments to the Committee will be made by the Secretary of Agriculture after consultation with the Secretary of

Health and Human Services to ensure that recommendations made by the Committee take into account the needs of the diverse groups served by the Department.

The full Committee expects to meet at least once a year by teleconference or in-person, and the meetings will be announced in the **Federal Register**. The subcommittees will meet as deemed necessary by the chairperson through working group meetings in an open public forum. Subcommittees also may meet through teleconference or by computer-based conferencing (Webinars). Subcommittees may invite technical experts to present information for consideration by the subcommittee. The subcommittee meetings will not be announced in the **Federal Register**. FSIS will announce the agenda and subcommittee working group meetings through the Constituent Update, available online at: *http://www.fsis.usda.gov/cu.*

NACMCF holds subcommittee meetings in order to accomplish the work of NACMCF; all subcommittee work is reviewed and approved during a public meeting of the full Committee, as announced in the **Federal Register**. All data and records available to the full Committee are expected to be available to the public when the full Committee reviews and approves the work of the subcommittee. Advisory Committee members are expected to attend all in-person meetings during the two-year term to ensure the smooth functioning of the advisory committee. However, on rare occasions, attendance through teleconferencing may be permitted.

Members must be prepared to work outside of scheduled Committee and subcommittee meetings and may be required to assist in document preparation. Committee members serve on a voluntary basis; however, travel expenses and per diem reimbursement are available.

Regarding Nominees Who Are Selected

All SGE and Federal government employee nominees who are selected must complete the Office of Government Ethics (OGE) 450 Confidential Financial Disclosure Report before rendering any advice or before their first meeting. With the exception of the consumer representative committee member, all committee members will be reviewed pursuant to 18 U.S.C. 208 for conflicts of interest relating to specific NACMCF work charges, and financial disclosure updates will be required annually. Members subject to financial disclosure must report any changes in financial holdings requiring additional disclosure. OGE 450 forms are available on-line at: *https://www2.oge.gov/web/oge.nsf/Confidential%20Financial%20Disclosure.*

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS 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: December 1, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016–29271 Filed 12–6–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

White River National Forest; Eagle County, CO El Jebel Administrative Sites, Upper and Lower Parcels, Conveyance Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service is proposing to convey two adjacent parcels of land, and the associated water rights and mineral estate in El Jebel, Colorado pursuant to the Forest Service Facility Realignment and Enhancement Act of 2005 Public Law 109–54; 16 U.S.C. 580d note, as amended by Public Law 112–74, Title IV, Sec. 421. The property is proposed to be sold as two parcels. The Lower Parcel is approximately 40 acres and is predominantly riparian in nature and the Upper Parcel is approximately 30 acres and consists of three residences, one mobile home pad, horse pastures, and outdoor equipment storage. A conservation easement or deed restriction intended to protect the wetlands, floodplains, aquatic, botanical, wildlife resources, and future public access may be placed on the Lower Parcel at the time of sale. The property may be sold directly to an identified purchaser or may be sold under competitive bidding procedures. The method of sale will be determined at a later date. Conveying the parcel will help the Forest Service to streamline its administrative sites and create a more efficient pattern of land ownership in Eagle County. The proposal includes a project-specific forest plan amendment.

DATES: Comments concerning the scope of the analysis must be received by January 23, 2017. The draft environmental impact statement (EIS) is expected to be available for public review in summer 2017 and the final EIS is expected in winter 2018.

ADDRESSES: Send written comments to Scott Fitzwilliams, Forest Supervisor c/

o Carole Huey, White River National Forest, 900 Grand Avenue, Glenwood Springs, CO 81601. Comments may also be submitted via *https://cara.ecosystem-management.org/Public//CommentInput?Project=50663,* email to *clhuey@fs.fed.us,* or via facsimile to (970) 945–3266.

FOR FURTHER INFORMATION CONTACT: Additional information related to the project can be obtained from the project Web page: *http://www.fs.fed.us/nepa/fs-usda-pop.php/?project=50663* or Carole Huey, Lands and Conveyance Program Manager, White River National Forest, 900 Grand Avenue, Glenwood Springs, CO 81601. Ms. Huey can be reached by phone at (970) 945–3219 or by email at *clhuey@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

Responsible Official: The Responsible Official is James S. Bedwell, Director of Recreation, Lands, and Minerals for the Rocky Mountain Region.

Nature of Decision To Be Made: Based on the analysis that will be documented in the forthcoming EIS, the Responsible Official will decide whether or not to implement, in whole or in part, the Proposed Action or another alternative that may be developed by the Forest Service as a result of scoping.

Scoping Process: This notice of intent initiates the scoping process, which guides the development of the EIS. The Forest Service is soliciting comments from Federal, State and local agencies and other individuals or organizations that may be interested in or affected by implementation of the proposed project. Public questions and comments regarding this proposal are an integral part of this environmental analysis process. Input provided by interested and/or affected individuals, organizations and governmental agencies will be used to identify alternative actions and resource issues that will be analyzed in the EIS.

Comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. A public open house meeting will discuss the proposed action on December 8, 2016 from 5:30–7:00 p.m., (Mountain Standard Time) at the Eagle County Community Center located at 0020 Eagle County Drive, El Jebel, CO 81623. The meeting will be held in the Mt. Sopris Room.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however anonymous commenters would not have standing to file an objection. Those who submit comments will have eligibility to file an objection following the procedure laid out in 36 CFR 218.8. There will be an additional opportunity to comment when the Notice of Availability of the Draft EIS is published in the **Federal Register**.

For objection eligibility, each individual or representative from each entity submitting written comments must either sign the comment or verify identity upon request. Individuals and organizations wishing to be eligible to object must meet the information requirements in 36 CFR 218.5.

Dated: December 1, 2016.

James S. Bedwell,

Director of Recreation, Lands and Minerals, Rocky Mountain Region (R–2), USDA Forest Service.

[FR Doc. 2016–29305 Filed 12–6–16; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Announcement of Grant Application Deadlines and Funding Levels

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Solicitation of Applications (NOSA), Household Water Well System Grant Program.

SUMMARY: The Rural Utilities Service (RUS) announces its Household Water Well System (HWWS) Grant Program application window for fiscal year (FY) 2017. RUS will make grants to qualified private non-profit organizations to establish lending programs for homeowners to borrow up to $11,000 to construct or repair household water wells for an existing home. The HWWS Grant Program is authorized under 7 U.S.C. 1926e. Regulations may be found at 7 CFR part 1776.

This year RUS will assign administrative discretion points to applications that:

1. Direct loans to rural areas where according to the American Community Survey data by census tracts show that at least 20 percent of the population is living in poverty.

2. Direct loans to areas which lack running water, flush toilets, and modern sewage disposal systems, and areas which have open sewers and high rates of disease caused by poor sanitation, in particular, colonias or Substantially Underserved Trust Areas.

3. Direct loans to rural areas impacted by severe drought.

DATES: The deadline for completed applications for a HWWS grant is February 6, 2017. Applications in either paper or electronic format must be postmarked or time-stamped electronically on or before the deadline. Late applications will be ineligible for grant consideration.

ADDRESSES: Submit applications to the following addresses:

1. *Electronic applications: http://www.grants.gov/.* Submit electronic applications through *Grants.gov*, following the instructions on that Web site.

2. *Paper applications:* Water Programs Division, Rural Development, Rural Utilities Service, STOP: 1570, Room 2234–S, 1400 Independence Avenue SW., Washington, DC 20250–1570.

Obtain application guides and materials for the HWWS Grant Program electronically or in paper format from the following addresses:

1. *Electronic copies: http://www.rd.usda.gov/programs-services/household-water-well-system-grants*;

2. *Paper copies:* Water Programs Division, Rural Utilities Service, STOP: 1570, Room 2234–S, 1400 Independence Avenue SW., Washington, DC 20250–1570 or call (202) 720–9583.

FOR FURTHER INFORMATION CONTACT: Derek Jones, Community Programs Specialist, Water and Environmental Programs, Rural Utilities Service, Rural Development, U.S. Department of Agriculture, STOP 1570, Room 2234–S, 1400 Independence Avenue SW., Washington, DC 20250–1570;. Telephone: (202) 720–9640, fax: (202) 690–0649, email: *derek.jones@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service, USDA.

Funding Opportunity Title: HWWS Grant Program.

Announcement Type: Grant—Solicitation of Applications.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.862.

Due Date for Applications: February 6, 2017.

Items in Supplementary Information

I. Funding Opportunity: Description of the HWWS Grant Program.

II. Award Information: To be determined.

III. Eligibility Information: Who is eligible, what kinds of projects are eligible, what criteria determine basic eligibility.

IV. Application and Submission Information: Where to get application materials, what constitutes a completed application, how and where to submit applications, deadlines, items that are eligible.

V. Application Review Information: Considerations and preferences, scoring criteria, review standards, selection information.

VI. Award Administration Information: Award notice information, award recipient reporting requirements.

VII. Agency Contacts: Web site, phone, fax, email, contact name.

VIII. Non-discrimination Statement: USDA non-discrimination statement, how to file a complaint, persons with disabilities.

I. Funding Opportunity

A. Program Description

The HWWS Grant Program has been established to help individuals with low to moderate incomes finance the costs of household water wells that they own or will own. The HWWS Grant Program is authorized under Section 306E of the Consolidated Farm and Rural Development Act (CONACT), 7 U.S.C. 1926e. The CONACT authorizes RUS to make grants to qualified private non-profit organizations to establish lending programs for household water wells.

As the grant recipients, private non-profit organizations will receive HWWS grants to establish lending programs that will provide water well loans to individuals. The individuals, as loan recipients, may use the loans to construct, refurbish, and service their household well systems. A loan may not exceed $11,000 and will have a term up to 20 years at a one percent annual interest rate.

B. Background

RUS supports the sound development of rural communities and the growth of our economy without endangering the environment. RUS provides financial and technical assistance to help communities bring safe drinking water and sanitary, environmentally sound waste disposal facilities to Rural Americans in greatest need.

Central water systems may not be the only or best solution to drinking water problems. Distance or physical barriers make public central water systems costly to deploy in remote areas. A significant number of geographically isolated households without water service might require individual wells rather than connections to new or existing community systems. The goal of RUS is not only to make funds available to those communities most in need of potable water but also to ensure that facilities used to deliver drinking water are safe and affordable. There is a role for private wells in reaching this goal.

C. Purpose

The purpose of the HWWS Grant Program is to provide funds to private non-profit organizations to assist them in establishing loan programs from which individuals may borrow money for HWWS. Faith-based organizations are eligible and encouraged to apply for this program. Applicants must show that the project will provide technical and financial assistance to eligible individuals to remedy household well problems.

Due to the limited amount of funds available typically available under the HWWS Grant Program, the RUS anticipates that 10 applications may be funded from FY 2017 funds. Applications from existing HWWS grant recipients are acceptable and will be evaluated as new applications.

II. Award Information

Funding Instrument Type: Grant.

Available Funds: To be announced.

Anticipated Number of Awards: 10.

Length of Project Periods: 12-month project.

Assistance Instrument: Grant Agreement with successful applicants before any grant funds are disbursed.

III. Eligibility Information

A. Who is eligible for grants?

1. An organization is eligible to receive a HWWS grant if it:

a. Has an active registration with current information in the System for Award Management (SAM) and has a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number.

b. Is a private, non-profit organization.

c. Is legally established and located within one of the following:

(1) A state within the United States
(2) The District of Columbia
(3) The Commonwealth of Puerto Rico
(4) A United States territory.

d. Has the legal capacity and authority to carry out the grant purpose.

e. Has sufficient expertise and experience in lending activities.

f. Has sufficient expertise and experience in promoting the safe and productive use of individually-owned HWWS and ground water.

g. Has no delinquent debt to the federal government or no outstanding judgments to repay a federal debt.

h. Demonstrates that it possesses the financial, technical, and managerial capability to comply with federal and State laws and requirements, and

i. Is not a corporation that has been convicted of a felony (or had an officer or agent acting on behalf of the corporation convicted of a felony) within the past 24 months. Any Corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability is not eligible.

2. An individual is ineligible to receive a HWWS grant. An individual may receive a loan from an organization receiving a grant award.

B. What are the basic eligibility requirements for a project?

1. *Project Eligibility.* To be eligible for a grant, the project must:

a. Be a revolving loan fund created to provide loans to eligible individuals to construct, refurbish, and service individually-owned HWWS (see 7 CFR 1776.11 and 1776.12). Loans may not be provided for home sewer or septic system projects.

b. Be established and maintained by a private, non-profit organization.

c. Be located in a rural area. Rural area is defined as locations other than cities or towns of more than 50,000 people and the contiguous and adjacent urbanized area of such towns and cities.

2. *Required Matching Contributions.* Grant applicants must provide written evidence of a matching contribution of at least 10 percent from sources other than the proceeds of a HWWS grant. In-kind contributions will not be considered for the matching requirement. Please see 7 CFR 1776.9 for the requirement.

3. *Other—Requirements.*

a. DUNS Number. The applicant for a grant must supply a DUNS number as part of an application. The Standard Form 424 (SF–424) contains a field for the DUNS number. The applicant can obtain the DUNS number free of charge by calling Dun and Bradstreet. Please see *http://fedgov.dnb.com/webform* for more information on how to obtain a DUNS number or how to verify your organization's number.

b. Prior to submitting an application, the applicant must register in System for Award Management (SAM).

(1) Applicants may register for SAM at *https://www.sam.gov/portal/public/SAM/.*

(2) The SAM registration must remain active with current information at all times while RUS is considering an application or while a Federal grant award or loan is active. To maintain the registration in the SAM database the applicant must review and update the information in the SAM database

annually from date of initial registration or from the date of the last update. The applicant must ensure that the information in the database is current, accurate, and complete.

c. Eligibility to receive a HWWS loan will be based on the following criteria:

(1) An individual must be a member of a household of which the combined household income of all members does not exceed 100 percent of the median non-metropolitan household income for the State or territory in which the individual resides. Household income is the total income from all sources received by each adult household member for the most recent 12-month period for which the information is available. It does not include income earned or received by dependent children under 18 years old or other benefits that are excluded by federal law. The non-metropolitan household income must be based on the 5-year income data from the American Community Survey (ACS) or, if needed, other data from the United States Bureau of the Census.

RUS publishes a list of income exclusions in 7 CFR 3550.54(b). Also, the Department of Housing and Urban Development published a list of income exclusions in the **Federal Register** on May 20, 2014, at 79 FR 28938 (see ''Federally Mandated Exclusions'').

(2) The loan recipient must own and occupy the home being improved with the proceeds of the Household Water Well loan or be purchasing the home to occupy under a legally enforceable land purchase contract which is not in default by either the seller or the purchaser.

(3) The home being improved with the water well system must be located in a rural area.

(4) The loan for a water well system must not be associated with the construction of a new dwelling.

(5) The loan must not be used to substitute a water well system for water service available from collective water systems. (For example, a loan may not be used to restore an old well abandoned when a dwelling was connected to a water district's water line.)

(6) The loan recipient must not be suspended or debarred from participation in Federal programs.

IV. Application and Submission Information

A. Where To Get Application Information

The HWWS Grant Application Guide (Application Guide), copies of necessary forms and samples, and the HWWS Grant Program regulation are available from these sources:

1. Internet for electronic copies: *http://www.grants.gov/* or *http://www.rd.usda.gov/programs-services/household-water-well-system-grants*;

2. Water and Environmental Programs for paper copies: RUS, Water Programs Division, STOP 1570, Room 2233–S, 1400 Independence Avenue SW., Washington, DC 20250–1570, Telephone: (202) 720–9589, Fax: (202) 690–0649.

B. Content and Form of Application Submission

1. Rules and Guidelines:

a. Detailed information on each item required can be found in the HWWS Grant Program regulation (7 CFR part 1776) and the Application Guide. Applicants are strongly encouraged to read and apply both the regulation and the Application Guide. This Notice does not change the requirements for a completed application for any form of HWWS financial assistance specified in the regulation. The regulation and Application Guide provide specific guidance on each of the items listed.

b. Applications should be prepared in conformance with the provisions in 7 CFR part 1776, subpart B, and departmental and other applicable regulations including 2 CFR parts 180, 182, 200, 400, and 421, or any successor regulations. Applicants should use the Application Guide which contains instructions and other important information in preparing their application. Completed applications must include the items found in the checklist in the next paragraph.

2. Checklist of Items in Completed Application Packages:

a. DUNS Number. The applicant for a grant must supply a Dunn and Bradstreet Data Universal Numbering System (DUNS) number as part of an application. The Standard Form 424 (SF–424) contains a field for the DUNS number. The applicant can obtain the DUNS number free of charge by calling Dun and Bradstreet. Please see *http://fedgov.dnb.com/webform* for more information on how to obtain a DUNS number or how to verify your organization's number.

b. Prior to submitting an application, the applicant must register in the System for Award Management (SAM).

(1) Applicants may register for the SAM at: *https://www.sam.gov/portal/public/SAM/*.

(2) The SAM registration must remain active with current information at all times while RUS is considering an application or while a Federal Grant Award or loan is active. To maintain the registration in the SAM database the applicant must review and update the information in the SAM database annually from date of initial registration or from the date of the last update. The applicant must ensure that the information in the database is current, accurate, and complete.

(3) Your organization must be listed in the SAM. If you have not used *Grants.gov* before, you will need to register with the SAM and the Credential Provider. New registrations can take three to five business days to process. Updating or renewing an active registration has a shorter turnaround, 24 hours. Registrations in SAM are active for one year. The SAM registers your organization, housing your organizational information and allowing *Grants.gov* to use the information to verify your identity. The DUNS number, Taxpayer Identification Number (TIN), and name and address of the applicant organization must match SAM data files.

c. The electronic and paper application process requires forms with the prefixes RD and SF as well as supporting documents and certifications.

Application Items

(1) SF–424, ''Application for Federal Assistance''.

(2) SF–424A, ''Budget Information—Non-Construction Programs''.

(3) SF–424B, ''Assurances—Non-Construction Programs''.

(4) SF–LLL, ''Disclosure of Lobbying Activity''.

(5) Form RD 400–1, ''Equal Opportunity Agreement''.

(6) Form RD 400–4, ''Assurance Agreement (Under Title VI, Civil Rights Act of 1964).

(7) Project Proposal, Project Summary, Needs Assessment, Project Goals and Objectives, Project Narrative.

(8) Work Plan.

(9) Budget and Budget Justification.

(10) Evidence of Legal Authority and Existence.

(11) Documentation of private non-profit status and Internal Revenue Service (IRS) Tax Exempt Status.

(12) List of Directors and Officers.

(13) Financial information and sustainability (narrative).

(14) Assurances and certifications of compliance with other Federal Statutes.

The forms in items 1 through 6 must be completed and signed where appropriate by an official of your organization who has authority to obligate the organization legally. RD forms are used by programs under the RD mission area. Standard forms (SF) are used government-wide. In addition

to the sources listed in section A, the forms may be accessed electronically through the RD Web site at *http://www.rd.usda.gov/publications.*

See section V, ''Application Review Information,'' for instructions and guidelines on preparing Items 7 through 13.

3. *Compliance with Other Federal Statutes.* The applicant must provide evidence of compliance with other Federal statutes and regulations, including, but not limited to the following:

a. 7 CFR part 15, subpart A—Nondiscrimination in Federally Assisted Programs of the Department of Agriculture—Effectuation of Title VI of the Civil Rights Act of 1964.

b. 2 CFR part 417—Governmentwide Debarment and Suspension (Nonprocurement), or any successor regulations.

c. 7 CFR part 3052—Audits of States, Local Governments, and Non-profit Organizations, or any successor regulations.

d. Subpart B of 2 CFR part 421, which adopts the Governmentwide implementation (2 CFR part 182) of the Drug-Free Workplace Act.

e. Executive Order 13166, ''Improving Access to Services for Persons with Limited English Proficiency.'' For information on limited English proficiency and agency-specific guidance go to *http://www.lep.gov/.*

f. Federal Obligation Certification on Delinquent Debt.

C. How many copies of an application are required?

1. *Applications Submitted on Paper.* Submit one signed original and two additional copies. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, and have original signatures. Do not include organizational brochures or promotional materials.

2. *Applications Submitted Electronically.* Additional paper copies are unnecessary if the application is submitted electronically through *http://www.grants.gov/.*

D. How and Where To Submit an Application

1. Submitting Paper Applications:

a. For paper applications, mail or ensure delivery of an original paper application (no stamped, photocopied, or initialed signatures) and two copies by the deadline date to:

Rural Development, Rural Utility Service, Water Programs Division, STOP 1570, Room 2234–S, 1400 Independence Avenue SW., Washington, DC 20250–1570, Telephone: (202) 720–9583.

Submit paper applications marked ''Attention: Water and Environmental Programs.''

b. Applications must show proof of mailing or shipping by one of the following:

(1) A legibly dated U.S. Postal Service (USPS) postmark;

(2) A legible mail receipt with the date of mailing stamped by the USPS; or,

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

c. If a deadline date falls on a weekend, it will be extended to the following Monday. If the date falls on a federal holiday, it will be extended to the next business day.

d. Due to screening procedures at the Department of Agriculture, packages arriving via the USPS are irradiated, which can damage the contents and delay delivery. RUS encourages applicants to consider the impact of this procedure in selecting an application delivery method.

2. Submitting Electronic Applications:

a. Applications will not be accepted by fax or electronic mail.

b. Electronic applications for grants will be accepted if submitted through *Grants.gov* at *http://www.grants.gov/.*

c. Applicants must preregister successfully with *Grants.gov* to use the electronic applications option. Application information may be downloaded from *Grants.gov* without preregistration.

d. Applicants who apply through *Grants.gov* should submit their electronic applications before the deadline.

e. *Grants.gov* contains full instructions on all required passwords, credentialing, and software. Follow the instructions at *Grants.gov* for registering and submitting an electronic application.

f. *Grants.gov* has two preregistration requirements: A DUNS number and an active registration in SAM. See the ''Checklist of Items in Completed Application Packages'' for instructions on obtaining a DUNS number and registering in the SAM.

g. You must be registered with *Grants.gov* before you can submit an electronic grant application.

(1) You must register at *Grants.gov: http://www.grants.gov/applicants/get_registered.jsp.*

(2) Organization registration user guides and checklists are also available at *Grants.gov.*

(3) *Grants.gov* requires some credentialing and online authentication procedures. When an applicant organization is registered with SAM, the organization designates a point of contact who receives a password authorizing the person to designate staff members who are allowed to submit applications electronically through *Grants.gov.* These authorized organization representatives must be registered with *Grants.gov* to receive a username and password to submit applications. These procedures may take several business days to complete.

(4) Some or all of the SAM and *Grants.gov* registration, credentialing and authorizations require updates. If you have previously registered at *Grants.gov* to submit applications electronically, please ensure that your registration, credentialing and authorizations are up to date well in advance of the grant application deadline.

h. To use *Grants.gov:*

(1) Follow the instructions on the Web site to find grant information.

(2) Download a copy of an application package.

(3) Complete the package off-line.

(4) Upload and submit the application via the *Grants.gov* Web site.

(5) If a system problem or technical difficulty occurs with an electronic application, please use the customer support resources available at the *Grants.gov* Web site.

(6) Again, RUS encourages applicants to take early action to complete the sign-up, credentialing and authorization procedures at *Grants.gov* before submitting an application at the Web site.

E. Deadlines

The deadline for paper and electronic submissions is February 6, 2017. Paper applications must be postmarked and mailed, shipped, or sent overnight no later than the closing date to be considered for FY 2017 grant funding. Electronic applications must have an electronic date and time stamp by midnight of February 6, 2017 to be considered on time. RUS will not accept applications by fax or email. Applications that do not meet the criteria above are considered late applications and will not be considered. RUS will notify each late applicant that its application will not be considered.

F. Funding Restrictions

1. Eligible Grant Purposes:

a. Grant funds must be used to establish and maintain a revolving loan fund to provide loans to eligible individuals for household water well systems.

b. Individuals may use the loans to construct, refurbish, rehabilitate, or

replace household water well systems up to the point of entry of a home. Point of entry for the well system is the junction where water enters into a home water delivery system after being pumped from a well.

c. Grant funds may be used to pay administrative expenses associated with providing HWWS loans.

2. Ineligible Grant Purposes:

a. Administrative expenses incurred in any calendar year that exceed 10 percent of the household water well loans made during the same period do not qualify for reimbursement.

b. Administrative expenses incurred before RUS executes a grant agreement with the recipient do not qualify for reimbursement.

c. Delinquent debt owed to the Federal Government does not qualify for reimbursement.

d. Grant funds may not be used to provide loans for household sewer or septic systems.

e. Household Water Well loans may not be used to pay the costs of water well systems for the construction of a new house.

f. Household Water Well loans may not be used to pay the costs of a home plumbing system.

V. Application Review Information

A. Criteria

This section contains instructions and guidelines on preparing the project proposal, work plan, and budget sections of the application. Also, guidelines are provided on the additional information required for RUS to determine eligibility and financial feasibility.

1. *Project Proposal.* The project proposal should outline the project in sufficient detail to provide a reader with a complete understanding of the loan program. Explain what will be accomplished by lending funds to individual well owners. Demonstrate the feasibility of the proposed loan program in meeting the objectives of this grant program. The proposal should include the following elements:

a. Project Summary. Present a brief project overview. Explain the purpose of the project, how it relates to RUS' purposes, how the project will be executed, what the project will produce, and who will direct it.

b. Needs Assessment. To show why the project is necessary, clearly identify the economic, social, financial, or other problems that require solutions. Demonstrate the well owners' need for financial and technical assistance. Quantify the number of prospective borrowers or provide statistical or narrative evidence that a sufficient number of borrowers will exist to justify the grant award. Describe the service area. Provide information on the household income of the area and other demographical information. Address community needs.

c. Project Goals and Objectives. Clearly state the project goals. The objectives should clearly describe the goals and be concrete and specific enough to be quantitative or observable. They should also be feasible and relate to the purpose of the grant and loan program.

d. Project Narrative. The narrative should cover in more detail the items briefly described in the Project Summary. Demonstrate the grant applicant's experience and expertise in promoting the safe and productive use of individually-owned household water well systems. The narrative should address the following points:

(1) Document the grant applicant's ability to manage and service a revolving fund. The narrative may describe the systems that are in place for the full life cycle of a loan from loan origination through servicing. If a servicing contractor will service the loan portfolio, the arrangement and services provided must be discussed.

(2) Show evidence of the availability of funds from sources other than the HWWS grant. Describe the contributions the project will receive from your organization, state agencies, local government, other federal agencies, non-government organizations, private industry, and individuals. The documentation should describe how the contributions will be used to pay your operational costs and provide financial assistance for projects.

(3) Demonstrate that the organization has secured commitments of significant financial support from other funding sources.

(4) List the fees and charges that borrowers will be assessed.

2. *Work Plan.* The work plan or scope of work must describe the tasks and activities that will be accomplished with available resources during the grant period. It must include who will carry out the activities and services to be performed and specific timeframes for completion. Describe any unusual or unique features of the project such as innovations, reductions in cost or time, or extraordinary community involvement.

3. *Budget and Budget Justification.* Use the Form SF–424A, Budget Information—Non-Construction Programs, to show your budget cost elements. The form summarizes resources as Federal and Non-Federal funds and costs. ''Federal'' refers only to the HWWS Grant Program for which you are applying. ''Non-Federal'' refers to resources from your organization, state agencies, local government, other federal agencies, non-government organizations, private industry, and individuals. Both Federal and Non-Federal resources shall be detailed and justified in the budget and narrative justification.

a. Provide a budget with line item detail and detailed calculations for each budget object class identified in section B of the Budget Information form (SF–424A). Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF–424.

b. Provide a narrative budget justification that describes how the categorical costs are derived for all capital and administrative expenditures, the matching contribution, and other sources of funds necessary to complete the project. Discuss the necessity, reasonableness, and allocability of the proposed costs.

c. If the grant applicant will use a servicing contractor, the fees may be reimbursed as an administrative expense as provided in 7 CFR 1776.13. These fees must be discussed in the budget narrative. If the grant applicant will hire a servicing contractor, it must demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 134 (currently set at $100,000).

d. The indirect cost category should be used only when the grant applicant currently has an indirect cost rate approved by the Department of Agriculture or another cognizant Federal agency. A grant applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the grant applicant is in the process of initially developing or renegotiating a rate, the grant applicant shall submit its indirect cost proposal to the cognizant agency immediately after the applicant is advised that an award will be made. In no event, shall the indirect cost proposal be submitted later than three months after the effective date of the award.

4. *Evidence of Legal Authority and Existence.* The applicant must provide satisfactory documentation that it is

legally recognized under state or Tribal and Federal law as a private non-profit organization. The documentation also must show that it has the authority to enter into a grant agreement with RUS and to perform the activities proposed under the grant application. Satisfactory documentation includes, but is not limited to, certificates from the Secretary of State, copies of state/Tribal statutes or laws establishing your organization, and copies of your organization's articles of incorporation and bylaws. Letters from IRS awarding tax-exempt status are not considered adequate evidence.

5. *List of Directors and Officers.* The applicant must submit a certified list of directors and officers with their respective terms.

6. *IRS Tax Exempt Status.* The applicant must submit evidence of tax exempt status from the Internal Revenue Service.

7. *Financial Information and Sustainability.* The applicant must submit pro forma balance sheets, income statements, and cash flow statements for the last three years and projections for three years. Additionally, the most recent audit of the applicant's organization must be submitted.

B. Evaluation Criteria

Grant applications that are complete and eligible will be scored competitively based on the following scoring criteria:

Scoring criteria	Points
Degree of expertise and experience in promoting the safe and productive use of individually-owned household water well systems and ground water.	Up to 30 points.
Degree of expertise and successful experience in making and servicing loans to individuals	Up to 20 points.
Percentage of applicant contributions. Points allowed under this paragraph will be based on written evidence of the availability of funds from sources other than the proceeds of a HWWS grant to pay part of the cost of a loan recipient's project. In-kind contributions will not be considered. Funds from other sources as a percentage of the HWWS grant and points corresponding to such percentages are as follows:	
0 to 9 percent	Ineligible.
10 to 25 percent	5 points.
26 to 30 percent	10 points.
31 to 50 percent	15 points.
51 percent or more	20 points.
Extent to which the work plan demonstrates a well thought out, comprehensive approach to accomplishing the objectives of this part, clearly defines who will be served by the project, and appears likely to be sustainable.	Up to 20 points.
Extent to which the goals and objectives are clearly defined, tied to the work plan, and measurable	Up to 10 points.
Lowest ratio of projected administrative expenses to loans advanced	Up to 10 points.
Administrator's discretion, considering such factors as:	
Creative outreach ideas for marketing HWWS loans to rural residents; factors include:	Up to 10 points.
1. Directs loans to rural areas where according to the American Community Survey data by census tracts show that at least 20 percent of the population is living in poverty. Directs loans to areas which lack running water, flush toilets, and modern sewage disposal systems, and areas which have open sewers and high rates of disease caused by poor sanitation, in particular, colonias or Substantially Underserved Trust Areas.	
2. Areas impacted by severe drought.	

C. Review Standards

1. Incomplete applications as of the deadline for submission will not be considered. If an application is determined to be incomplete, the applicant will be notified in writing and the application will be returned with no further action.

2. Ineligible applications will be returned to the applicant with an explanation.

3. Complete, eligible applications will be evaluated competitively by a review team, composed of at least two RUS employees selected from the Water Programs Division. They will make overall recommendations based on the program elements found in 7 CFR part 1776 and the review criteria presented in this notice. They will award points as described in the scoring criteria in 7 CFR 1776.9 and this notice. Each application will receive a score based on the averages of the reviewers' scores and discretionary points awarded by the RUS Administrator.

4. Applications will be ranked and grants awarded in rank order until all grant funds are expended.

5. Regardless of the score an application receives, if RUS determines that the project is technically infeasible, RUS will notify the applicant, in writing, and the application will be returned with no further action.

VI. Award Administration Information

A. Award Notices

RUS will notify a successful applicant by an award letter accompanied by a grant agreement. The grant agreement will contain the terms and conditions for the grant. The applicant must execute and return the grant agreement, accompanied by any additional items required by the award letter or grant agreement.

B. Administrative and National Policy Requirements

1. This notice, the 7 CFR part 1776, and the application guide implement the appropriate administrative and national policy requirements. Grant recipients are subject to the requirements in 7 CFR part 1776.

2. Direct federal grants, sub-award funds, or contracts under the HWWS Grant Program shall not be used to fund inherently religious activities, such as worship, religious instruction, or proselytization. Therefore, organizations that receive direct assistance should take steps to separate, in time or location, their inherently religious activities from the services funded under the HWWS Grant Program. Regulations for the Equal Treatment for Faith-based Organizations are contained in 7 CFR part 16, which includes the prohibition against federal funding of inherently religious activities.

C. Reporting

1. *Performance Reporting.* All recipients of HWWS Grant Program financial assistance must provide quarterly performance activity reports to RUS until the project is complete and the funds are expended. A final

performance report is also required. The final report may serve as the last annual report. The final report must include an evaluation of the success of the project.

2. *Financial Reporting.* All recipients of HWWS Grant Program financial assistance must provide an annual audit, beginning with the first year a portion of the financial assistance is expended. The Non-Federal Entity (formerly called Grantee) will provide an audit report or financial statements as follows:

a. Non-Federal Entities expending $500,000 or more Federal funds per fiscal year will submit an audit conducted in accordance with 2 CFR part 200 or successor guidance. The audit will be submitted within nine months after the Non-Federal Entity's fiscal year. Additional audits may be required if the project period covers more than one fiscal year.

b. Non-Federal Entities expending less than $500,000 will provide annual financial statements covering the grant period, consisting of the organization's statement of income and expense and balance sheet signed by an appropriate official of the organization. Financial statements will be submitted within 90 days after the Non-Federal Entity's fiscal year.

3. *Recipient and Subrecipient Reporting.* The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

a. First Tier Sub-Awards of $25,000 or more in non-Recovery Act funds (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov/* no later than the end of the month following the month the obligation was made.

b. The Total Compensation of the Recipient's Executives (five most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *https://www.sam.gov/portal/public/SAM/* by the end of the month following the month in which the award was made.

c. The Total Compensation of the Subrecipient's Executives (5 most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

VII. Agency Contacts

A. Web site: http://www.rd.usda.gov/programs-services/household-water-well-system-grants

B. Phone: 202–720–9640.

C. Fax: 202–690–0649.

D. Email: derek.jones@wdc.usda.gov.

E. Main point of contact: Derek Jones, Community Programs Specialist, Water Programs Division, Water and Environmental Programs, RUS, Rural Development, U.S. Department of Agriculture.

VIII. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *http://www.ascr.usda.gov/complaint_filing_cust.html* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by:

(1) *By mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410;

(2) *Fax:* (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Dated: November 7, 2016.

Brandon McBride,

Administrator, Rural Utilities Service.

[FR Doc. 2016–29336 Filed 12–6–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Announcement of Grant and Loan Application Deadlines

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Solicitation of Applications (NOSA), Revolving Fund Program.

SUMMARY: The Rural Utilities Service (RUS) announces its Revolving Fund Program (RFP) application window for Fiscal Year (FY) 2017. The RFP is authorized under section 306(a)(2)(B) of the Consolidated Farm and Rural Development Act (Con Act), 7 U.S.C. 1926(a)(2)(B). Under the RFP, qualified private, non-profit organizations may receive RFP grant funds to establish a lending program for eligible entities. Eligible entities for the revolving loan fund will be the same entities eligible, under paragraph 1 or 2 of Section 306(a) of the Con Act, 7 U.S.C. 1926(a)(1) or (b)(2), to obtain a loan, loan guarantee, or grant from the RUS Water, Waste Disposal, and Wastewater loan and grant programs.

This year administrative discretion points may be awarded for work plans that:

1. Direct loans to the smallest communities with the lowest incomes emphasizing areas where according to the American Community Survey data by census tracts show that at least 20 percent of the population is living in poverty.

2. Direct loans to areas that lack running water, flush toilets, and modern sewage disposal systems, and areas which have open sewers and high rates of disease caused by poor sanitation, in particular, colonias or Substantially Underserved Trust Areas.

3. Direct loans that emphasize energy and water efficient components to reduce costs and increase sustainability of rural systems.

DATES: You may submit completed applications for grants on paper or electronically according to the following deadlines:

- Paper copies must be postmarked and mailed, shipped, or sent overnight

no later than February 6, 2017 to be eligible for FY 2017 grant funding. Late or incomplete applications will not be eligible for FY 2017 grant funding.

• Electronic copies must be received by February 6, 2017 to be eligible for FY 2017 grant funding. Late or incomplete applications will not be eligible for FY 2017 grant funding.

ADDRESSES: You may obtain application guides and materials for the RFP program at the Water and Environmental Programs (WEP) Web site: *http://www.rd.usda.gov/programs-services/water-waste-disposal-revolving-loan-funds.* You may also request application guides and materials by contacting Lisa Chesnel at (202) 720–0499.

Submit electronic grant applications at *http://www.grants.gov/* and follow the instructions on the Web site.

Submit completed paper applications for RFP grants to, Rural Utilities Service, Rural Development, U.S. Department of Agriculture, 1400 Independence Avenue SW., Room 2234, STOP 1570, Washington, DC 20250–1570. Applications should be marked Attention: Lisa Chesnel, Water and Environmental Programs.

FOR FURTHER INFORMATION CONTACT: Lisa Chesnel, Community Programs Specialist, Water and Environmental Programs, Rural Utilities Service, Rural Development, U.S. Department of Agriculture STOP 1570, Room 2234–S, 1400 Independence Avenue SW., Washington, DC 20250–1570; Telephone: (202) 720–0499: Fax: (202) 690–0649.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service (RUS), USDA.

Funding Opportunity Title: Grant Program to Establish a Fund for Financing Water and Wastewater Projects (Revolving Fund Program (RFP)).

Announcement Type: Notice of Solicitation of Applications.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.864.

Due Date for Applications: Applications must be mailed, shipped or submitted electronically through *Grants.gov* no later than February 6, 2017 to be eligible for FY 2017 grant funding.

Items in Supplementary Information

A. Program Description: Brief introduction to the RFP.

B. Federal Award Information: To be announced.

C. Eligibility Information: Who is eligible, what kinds of projects are eligible, what criteria determine basic eligibility.

D. Application and Submission Information: Where to get application materials, what constitutes a completed application, how and where to submit applications, deadlines, items that are eligible.

E. Application Review Information: Considerations and preferences, scoring criteria, review standards, selection information.

F. Federal Award Administration Information: Award notice information, award recipient reporting requirements.

G. Federal Awarding Agency Contacts: Web site, phone, fax, email, contact name.

H. Other Information: Non-discrimination Statement.

A. Program Description

Drinking water systems are basic and vital to both health and economic development. With dependable water facilities, rural communities can attract families and businesses that will invest in the community and improve the quality of life for all residents. Without dependable water facilities, the communities cannot sustain economic development.

RUS provides financial and technical assistance to help communities bring safe drinking water and sanitary, environmentally sound waste disposal facilities to rural Americans. It supports the sound development of rural communities and the growth of our economy without endangering the environment.

The Revolving Fund Program (RFP) was established under 7 U.S.C. part 1783 to assist communities with water or wastewater systems. Qualified private, non-profit organizations, who are selected for funding, will receive RFP grant funds to establish a lending program for eligible entities. Eligible entities for the revolving loan fund will be those entities eligible under 7 U.S.C.1926(a)(1) and (2) to obtain a loan, loan guarantee, or grant from the Water and Waste Disposal loan and grant programs administered by RUS. As grant recipients, the non-profit organizations will set up a revolving loan fund to provide loans to finance predevelopment costs of water or wastewater projects, or short-term small capital projects not part of the regular operation and maintenance of current water and wastewater systems. The amount of financing to an eligible entity shall not exceed $100,000.00 and shall be repaid in a term not to exceed 10 years. The rate shall be determined in the approved grant work plan.

B. Federal Award Information

Available funds: To be announced.

C. Eligibility Information

1. *Eligible Applicants.* An applicant is eligible to apply for the RFP grant if it:

a. Is a private, non-profit organization;

b. Is legally established and located within one of the following:

i. A state within the United States;

ii. The District of Columbia;

iii. The Commonwealth of Puerto Rico; or

iv. A United States territory;

c. Has the legal capacity and authority to carry out the grant purpose;

d. Has a proven record of successfully operating a revolving loan fund to rural areas;

e. Has capitalization acceptable to the Agency, and is composed of at least 51 percent of the outstanding interest or membership being citizens of the United States or individuals who reside in the United States after being legally admitted for permanent residence;

f. Has no delinquent debt to the Federal government or no outstanding judgments to repay a Federal debt;

g. Demonstrates that it possesses the financial, technical, and managerial capability to comply with Federal and state laws and requirements; and

h. Is not a corporation that has been convicted of a felony (or had an officer or agent acting on behalf of the corporation convicted of a felony) within the past 24 months. Any Corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability is not eligible.

2. *Cost Sharing or Matching:* Applicants must contribute at least 20 percent of funds from sources other than the proceeds of an RFP grant to pay part of the cost of a loan recipient's project. In-kind contribution will not be considered.

3. *Other: What are the basic eligibility requirements for a project?*

a. The following activities are authorized under the RFP statute:

i. Grant funds must be used to capitalize a revolving fund program for the purpose of providing direct loan financing to eligible entities for pre-development costs associated with proposed or with existing water and wastewater systems, or,

ii. Short-term costs incurred for equipment replacement, small-scale extension of services, or other small capital projects that are not part of the regular operations and maintenance activities of existing water and wastewater systems.

b. Grant funds may not be used to pay any of the following:

i. Payment of the Grant Recipient's administrative costs or expenses, or,

ii. Delinquent debt owed to the Federal Government.

D. Application and Submission Information

1. *Address to Request Application Package:*

a. The Internet: *http://www.rd.usda.gov/programs-services/water-waste-disposal-revolving-loan-funds* or *Grants.gov* Web site: *http://www.grants.gov/.*

b. For paper copies of these materials, you may call (202) 720–9583.

2. *Content and Form of Application Submission:*

a. You may file an application in either paper or electronic format. To be considered for support, you must be an eligible entity and must submit a complete application by the deadline date. Applicants should consult the cost principles and general administrative requirements for grants pertaining to their organizational type in order to prepare the budget and complete other parts of the application. You also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements. Applications should be prepared in conformance with 7 CFR part 1783, and departmental and other applicable regulations including 2 CFR parts 180, 182, 200, 400 and 421, or any successor regulations.

Whether you file a paper or an electronic application, you will need a DUNS number and must be registered in the System for Award Management (SAM). Detailed information on obtaining a DUNS number and registering for SAM may be found in section D(3).

b. Applicants must complete and submit the following forms to apply for a RFP grant:

i. Standard Form 424, ''Application for Federal Assistance''.

ii. Standard Form 424A, ''Budget Information—Non-Construction Programs''.

iii. Standard Form 424B, ''Assurances—Non-Construction Programs''.

iv. Standard Form LLL, ''Disclosure of Lobbying Activity''.

v. Form RD 400–1, ''Equal Opportunity Agreement''.

vi. Form RD 400–4, ''Assurance Agreement (Under Title VI, Civil Rights Act of 1964).

c. The project proposal should outline the project in sufficient detail to provide a reader with a complete understanding of how the loan program will work. Explain what you will accomplish by lending funds to eligible entities. Demonstrate the feasibility of the proposed loan program in meeting the objectives of this grant program. The proposal should cover the following elements:

i. Present a brief project overview. Explain the purpose of the project, how it relates to RUS's purposes, how you will carry out the project, what the project will produce, and who will direct it.

ii. Describe why the project is necessary. Demonstrate that eligible entities need loan funds. Quantify the number of prospective borrowers or provide statistical or narrative evidence that a sufficient number of borrowers will exist to justify the grant award. Describe the service area. Address community needs.

iii. Clearly state your project goals. Your objectives should clearly describe the goals and be concrete and specific enough to be quantitative or observable. They should also be feasible and relate to the purpose of the loan program.

iv. The narrative should cover in more detail the items briefly described in the Project Summary. It should establish the basis for any claims that you have substantial expertise in promoting the safe and productive use of revolving funds. In describing what the project will achieve, you should tell the reader if it also will have broader influence. The narrative should address the following points:

(1) Document your ability to administer and service a revolving fund in accordance with the provisions of 7 CFR part 1783.

(2) Document your ability to commit financial resources to establish the RFP with funds your organization controls. This documentation should describe the sources of funds other than the RFP grant that will be used to pay your operational costs and provide financial assistance for projects.

(3) Demonstrate that you have secured commitments of significant financial support from other funding sources, if appropriate.

(4) List the fees and charges that borrowers will be assessed.

v. The work plan must describe the tasks and activities that will be accomplished with available resources during the grant period. It must show the work you plan to do to achieve the anticipated outcomes, goals, and objectives set out for the RFP. The plan must:

(1) Describe the work to be performed by each person.

(2) Give a schedule or timetable of work to be done.

(3) Show evidence of previous experience with the techniques to be used or their successful use by others.

(4) Outline the loan program to include the following: specific loan purposes, a loan application process, priorities, borrower eligibility criteria, limitations, fees, interest rates, terms, and collateral requirements.

(5) Provide a marketing plan.

(6) Explain the mechanics of how you will transfer loan funds to the borrowers.

(7) Describe follow-up or continuing activities that should occur after project completion such as monitoring and reporting borrowers' accomplishments.

(8) Describe how the results will be evaluated. The evaluation criteria should be in line with the project objectives.

(9) List all personnel responsible for administering this program along with a statement of their qualifications and experience.

vi. The written justification for projected costs should explain how budget figures were determined for each category. It should indicate which costs are to be covered by grant funds and which costs will be met by your organization or other organizations. The justification should account for all expenditures discussed in the narrative. It should reflect appropriate cost-sharing contributions. The budget justification should explain the budget and accounting system proposed or in place. The administrative costs for operating the budget should be expressed as a percentage of the overall budget. The budget justification should provide specific budget figures, rounding off figures to the nearest dollar. Applicants should consult 2 CFR 200, Subpart E, ''Cost Principals,'' for information about appropriate costs for each budget category.

vii. In addition to completing the standard application forms, you must submit:

(1) Supplementary material that demonstrate that your organization is legally recognized under state or Tribal and Federal law. Satisfactory documentation includes, but is not limited to, certificates from the Secretary of State, or copies of state statutes or laws establishing your organization. Letters from the IRS awarding tax-exempt status are not considered adequate evidence.

(2) A certified list of directors and officers with their respective terms.

(3) Evidence of tax exempt status from the IRS.

(4) The most recent audit of your organization.

(5) The following financial statements:

(a) A pro forma balance sheet at start-up and for at least three additional years; Balance sheets, income statements, and cash flow statements for the last three years.

(b) If your organization has been formed less than three years, the financial statements should be submitted for the periods from inception to the present. Projected income and cash flow statements for at least three years supported by a list of assumptions showing the basis for the projections. The projected income statement and balance sheet must include one set of projections that shows the revolving loan fund only and a separate set of projections that shows your organization's total operations.

(6) Additional information to support and describe your plan for achieving the grant objectives. The information may be regarded as essential for understanding and evaluating the project and may be found in letters of support, as resolutions, policies, and other relevant documents. The supplements may be presented in appendices to the proposal.

d. Compliance with other federal statutes.

The applicant must provide evidence of compliance with other federal statutes, including but not limited to the following:

i. Debarment and suspension information is required in accordance with 2 CFR part 417 (Nonprocurement Debarment and Suspension) supplemented by 2 CFR part 180, if it applies. The section heading is ''What information must I provide before entering into a covered transaction with the Federal Government?'' located at 2 CFR 180.335. It is part of OMB's Guidance for Grants and Agreements concerning Government-wide Debarment and Suspension.

ii. All of your organization's known workplaces by including the actual address of buildings (or parts of buildings) or other sites where work under the award takes place. Workplace identification is required under the drug-free workplace requirements in Subpart B of 2 CFR part 421, which adopts the Government-wide implementation (2 CFR part 182) of the Drug-Free Workplace Act.

iii. 2 CFR parts 200 and 400 (Uniform Assistance Requirements, Cost Principles and Audit Requirements for Federal Awards).

iv. 2 CFR part 182 (Governmentwide Requirements for Drug-Free Workplace (Financial Assistance)) and 2 CFR part 421 (Requirements for Drug Free Workplace (Financial Assistance)).

v. Executive Order 13166, ''Improving Access to Services for Persons with Limited English Proficiency.'' For information on limited English proficiency and agency-specific guidance, go to *http://www.LEP.gov.*

e. Requirements for numbers of copies of submitted applications

i. Send or deliver paper applications by the U.S. Postal Service (USPS) or courier delivery services to: Water and Environmental Programs, Rural Utilities Service, 1400 Independence Avenue SW., Attention: Lisa Chesnel, Mail STOP 1570, Room 2233–S, Washington, DC, 20250–1570.

ii. For paper applications mail or ensure delivery of an original paper application (no stamped, photocopied, or initialed signatures) and two copies by the deadline date. The application and any materials sent with it become Federal records by law and cannot be returned to you.

iii. Electronically submitted applications:

(1). Applications will not be accepted by fax or electronic mail.

(2). Electronic applications for grants will be accepted if submitted through *Grants.gov*.

(3). Applicants must preregister successfully with *Grants.gov* to use the electronic applications option. Application information may be downloaded from *Grants.gov* without preregistration.

(4). Applicants who apply through *Grants.gov* should submit their electronic applications before the deadline.

(5). *Grants.gov* contains full instructions on all required passwords, credentialing, and software. Follow the instructions at *Grants.gov* for registering and submitting an electronic application.

(6). *Grants.gov* has two preregistration requirements: A DUNS number and an active registration in the SAM. See section D(3) below for instructions on obtaining a DUNS number and registering in the SAM.

3. *Unique entity identifier and System for Award Management (SAM).* The applicant for a grant must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number as part of an application. The Standard Form 424 (SF–424) contains a field for the DUNS number. The applicant can obtain the DUNS number free of charge by calling Dun and Bradstreet. Please see *http://fedgov.dnb.com/webform* for more information on how to obtain a DUNS number or how to verify your organization's number.

In accordance with 2 CFR part 25, whether applying electronically or by paper, the applicant must register in the System for Award Management (SAM) prior to submitting an application. Applicants may register for the SAM at *https://www.sam.gov/portal/SAM/#1.* The SAM registration must remain active with current information at all times while RUS is considering an application or while a Federal Grant award or loan is active. To remain registered in the SAM database the applicant must review and update the information in the SAM database annually from date of initial registration or from the date of the last update. The applicant must ensure that the information in the database is current, accurate, and complete.

4. *Submission Dates and Times.* You may submit completed applications for grants on paper or electronically according to the following deadlines:

a. Paper copies must be postmarked and mailed, shipped, or sent overnight no later than February 6, 2017 to be eligible for FY 2017 grant funding. Late or incomplete applications will not be eligible for FY 2017 grant funding.

b. Electronic copies must be received by February 6, 2017 to be eligible for FY 2017 grant funding. Late or incomplete applications will not be eligible for FY 2017 grant funding.

5. *Funding Restrictions.* Grant proceeds may be used solely to establish the revolving loan fund to provide loans to eligible entities for: Pre-development costs associated with proposed or existing water and wastewater projects, and short-term costs incurred for replacement equipment or other small capital projects not part of regular operations and maintenance of existing water and wastewater systems. Grant recipients may not use grant funds in any manner inconsistent with the purposes described in 7 CFR 1783.12 or in the terms of the grant agreement. Administrative expenses may, however, be paid or reimbursed from revolving loan fund assets that are not RFP grant funds, including revolved funds and case originally contributed by the grant recipient.

E. Application Review Information

Within 30 days of receiving your application, RUS will send you a letter of acknowledgment. Your application will be reviewed for completeness to determine if you included all of the items required. If your application is incomplete or ineligible, RUS will return it to you with an explanation. A review team, composed of at least two

RUS staff members, will evaluate all applications and proposals. They will make overall recommendations based on factors such as eligibility, application completeness, and conformity to application requirements. They will score the applications based on criteria in the following section.

1. *Criteria.* All applications that are complete and eligible will be ranked competitively based on the following scoring criteria:

a. Degree of expertise and successful experience in making and servicing commercial loans, with a successful record, for the following number of full years:

i. At least 1 but less than 3 years—5 points.

ii. At least 3 but less than 5 years—10 points.

iii. At least 5 but less than 10 years—20 points.

iv. 10 or more years—30 points.

b. Extent to which the work plan demonstrates a well thought out, comprehensive approach to accomplishing the objectives of this part, clearly defines who will be served by the project, clearly articulates the problem/issues to be addressed, identifies the service area to be covered by the RFP loans and appears likely to be sustainable; Up to 40 points.

c. Percentage of applicant contributions. Points allowed under this paragraph will be based on written evidence of the availability of funds from sources other than the proceeds of an RFP grant to pay part of the cost of a loan recipient's project. In-kind contributions will not be considered. Funds from other sources as a percentage of the RFP grant and points corresponding to such percentages are as follows:

i. Less than 20 percent—ineligible.

ii. At least 20 percent but less than 50 percent—10 points.

iii. 50 percent or more—20 points.

d. Extent to which the goals and objectives are clearly defined, tied to the work plan, and are measurable; Up to 15 points.

e. Lowest ratio of projected administrative expenses to loans advanced; Up to 10 points.

f. The evaluation methods for considering loan applications and making RFP loans are specific to the program, clearly defined, measurable, and are consistent with program outcomes; Up to 20 points.

g. Administrator's discretion points up to 10 points may be awarded. To the maximum extent possible, there should be an emphasis on high poverty areas in rural communities and rural areas with the lowest incomes, particularly those areas where at least 45 percent of children qualify for the National School Lunch Program.

Factors include:

i. Directs loans to the smallest communities with the lowest incomes emphasizing areas where according to the American Community Survey data by census tracts show that at least 20 percent of the population is living in poverty.

ii. Directs loans to areas which lack running water, flush toilets, and modern sewage disposal systems, and areas which have open sewers and high rates of disease caused by poor sanitation, in particular, colonias or Substantially Underserved Trust Areas.

iii. Directs loans that emphasize energy and water efficient components to reduce costs and increase sustainability of rural systems.

2. *Review and Selection Process.* RUS will rank all qualifying applications by their final score. Applications will be selected for funding, based on the highest scores and the availability of funding for RFP grants. Each applicant will be notified in writing of the score its application receives.

a. In making its decision about your application, RUS may determine that your application is:

i. Eligible and selected for funding,

ii. Eligible but offered fewer funds than requested,

iii. Eligible but not selected for funding, or

iv. Ineligible for the grant.

c. In accordance with 7 CFR part 1900, subpart B, you generally have the right to appeal adverse decisions. Some adverse decisions cannot be appealed. For example, if you are denied RUS funding due to a lack of funds available for the grant program, this decision cannot be appealed. However, you may make a request to the National Appeals Division (NAD) to review the accuracy of our finding that the decision cannot be appealed. The appeal must be in writing and filed at the appropriate regional office, which can be found at *www.nad.usda.gov* or by calling (703) 305–1166.

F. Federal Award Administration Information

1. *Federal Award Notices.* RUS generally notifies by mail applicants whose projects are selected for awards. However, the receipt of an award letter does not serve to authorize the applicant to commence performance under the award. RUS follows the award letter with an agreement containing terms and conditions for the grant. Applicants selected for funding will complete and return grant agreement, which outlines the terms and conditions of the grant award.

2. *Administrative and National Policy Requirements.* The items listed in Section D of this notice, the RFP program regulation and departmental and other regulations including 2 CFR parts 180, 182, 200, 400, 421 and any successor regulations implement the appropriate administrative and national policy requirements, which include but are not limited to:

a. SF–270, ''Request for Advance or Reimbursement,'' will be completed by the Non-Federal Entity and submitted to either the state or national office no more frequently than monthly.

b. Upon receipt of a properly completed SF–270, the funds will be requested through the field office terminal system. Ordinarily, payment will be made within 30 days after receipt of a proper request for reimbursement.

c. Non-Federal Entities may use women- and minority-owned banks (a bank which is owned at least 50 percent by women or minority group members) for the deposit and disbursement of funds.

3. *Reporting.* a. Any change in the scope of the project, budget adjustments of more than 10 percent of the total budget, or any other significant change in the project must be reported to and approved by the approval official by written amendment to the grant agreement. Any change not approved may be cause for termination of the grant.

b. Non-Federal Entities shall constantly monitor performance to ensure that time schedules are being met, projected work by time periods is being accomplished, and other performance objectives are being achieved. The Non-Federal Entity will provide project reports as follows:

i. SF–425, ''Financial Status Report (short form),'' and a project performance activity report will be required of all Non-Federal Entities on a quarterly basis, due 30 days after the end of each quarter.

ii. A final project performance report will be required with the last SF–425 due 90 days after the end of the last quarter in which the project is completed. The final report may serve as the last quarterly report.

iii. All multi-State Non-Federal Entities are to submit an original of each report to the National Office. Non-Federal Entities serving only one State are to submit an original of each report to the State Office. The project performance reports should detail, preferably in a narrative format,

activities that have transpired for the specific time period.

c. Financial reporting. The Non-Federal Entity will provide an audit report or financial statements as follows:

i. Non-Federal Entities expending $750,000 or more Federal funds per fiscal year will submit an audit conducted in accordance with 2 CFR part 200 The audit will be submitted within nine months after the Non-Federal Entity's fiscal year. Additional audits may be required if the project period covers more than one fiscal year.

ii. Non-Federal Entities expending less than $750,000 will provide annual financial statements covering the grant period, consisting of the organization's statement of income and expense and balance sheet signed by an appropriate official of the organization. Financial statements will be submitted within 90 days after the Non-Federal Entity's fiscal year.

iii. Recipient and Subrecipient Reporting. The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR part 170, § 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

(1) First Tier Sub-Awards of $25,000 or more in non-Recovery Act funds (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov* no later than the end of the month following the month the obligation was made.

(2) The Total Compensation of the Recipient's Executives (five most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *https://www.sam.gov/portal/SAM/#1* by the end of the month following the month in which the award was made.

(3) The Total Compensation of the Subrecipient's Executives (five most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

G. Federal Awarding Agency Contacts

1. Web site: *http://www.rd.usda.gov/programs-services/water-waste-disposal-revolving-loan-funds.* The RUS Web site maintains up-to-date resources and contact information for the RFP.

2. Phone: (202) 720–9640.

3. Fax: (202) 690–0649.

4. Email: *lisa.chesnel@wdc.usda.gov.*

5. Main point of contact: Lisa Chesnel, Community Programs Specialist, Water and Environmental Programs, Rural Utilities Service, Rural Development, U.S. Department of Agriculture.

H. Other Information

1. *USDA Non-Discrimination Statement.* In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

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(1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

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Brandon McBride,

Administrator, Rural Utilities Service.

[FR Doc. 2016–29335 Filed 12–6–16; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–81–2016]

Foreign-Trade Zone (FTZ) 134—Chattanooga, Tennessee; Notification of Proposed Production Activity; Volkswagen Group of America—Chattanooga Operations, LLC; (Passenger Motor Vehicles); Chattanooga, Tennessee

Volkswagen Group of America—Chattanooga Operations, LLC (VW) submitted a notification of proposed production activity to the FTZ Board for its facility in Chattanooga, Tennessee, within FTZ 134. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 25, 2016.

VW already has authority to produce passenger motor vehicles within Site 3 of FTZ 134. The current request would add foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt VW from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, VW would be able to choose the duty rates during customs entry procedures that apply to passenger motor vehicles (duty rate 2.5%) for the foreign-status materials/components noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include: Gasoline; diesel fuel, polyurea grease; hydraulic oil; polycarbamide grease; refrigerant; urea; clear lacquer; blending solvent; PVC finishing sheet; canvas covers; aluminum chassis plate; screw driver bits; software; spindle drives; aux-in ports; optical fiber cable; white motor vehicle bodies; and, prototype vehicles

and engines (duty rate ranges from free to 5.7% + .013/KG).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 17, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: November 30, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29348 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2019]

Reorganization of Foreign-Trade Zone 17; (Expansion of Service Area) Under Alternative Site Framework; Kansas City, Kansas

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Greater Kansas City Foreign Trade Zone, Inc., grantee of Foreign-Trade Zone 17, submitted an application to the Board (FTZ Docket B–16–2016, docketed March 31, 2016) for authority to expand the service area of the zone to include Atchison, Jefferson and Franklin Counties, Kansas, as described in the application, adjacent to the Kansas City Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (81 FR 19551–19552, April 5, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby orders:

The application to reorganize FTZ 17 to expand the service area under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Signed at Washington, DC, this 29 day of November 2016.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29356 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2023]

Approval of Expansion of Subzone 124D; LOOP LLC; Lafourche and St. James Parishes, Louisiana

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of subzones for specific uses;

Whereas, the Port of South Louisiana, grantee of Foreign-Trade Zone 124, has made application to the Board to expand Subzone 124D-Site 1 on behalf of LOOP LLC to include an additional parcel in Cut Off, Louisiana (FTZ Docket B–54–2016, docketed August 16, 2016);

Whereas, notice inviting public comment has been given in the **Federal Register** (81 FR 56582, August 22, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's memorandum, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby approves the expansion of Subzone 124D on behalf of LOOP LLC, as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.13.

Dated: November 29, 2016.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance Alternate Chairman Foreign-Trade Zones Board.

[FR Doc. 2016–29344 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–82–2016]

Foreign-Trade Zone (FTZ) 226—Merced County, California; Notification of Proposed Production Activity; Brake Parts Inc; (Automotive Parts Kitting); Patterson, California

Brake Parts Inc (BPI) submitted a notification of proposed production activity to the FTZ Board for its facility in Patterson, California, within FTZ 226. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 30, 2016.

The BPI facility is located within Site 14 of FTZ 226. The facility is used for the kitting of aftermarket automotive parts. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt BPI from customs duty payments on the foreign-status components used in export production. On its domestic sales, BPI would be able to choose the duty rates during customs entry procedures that apply to master cylinder kits, brake drum kits, brake pad kits, brake shoe kits and brake caliper kits (duty rate ranges from free to 2.5%) for the foreign-status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: Rubber O-rings; rubber seals; rubber brake components; paperboard corrugated

boxes; steel hex bolts; steel bolts; steel brake clips; galvanized cast iron brake brackets; master cylinders; brake drums; brake pads; brake shoes; and, wheel cylinders (duty rate ranges from free to 2.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 17, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

FOR FURTHER INFORMATION CONTACT: Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: December 1, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29349 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2021]

Reorganization of Foreign-Trade Zone 93; (Expansion of Service Area) Under Alternative Site Framework; Raleigh-Durham, North Carolina

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Triangle J Council of Governments, grantee of Foreign-Trade Zone 93, submitted an application to the Board (FTZ Docket B–36–2016, docketed May 17, 2016) for authority to expand the service area of the zone to include Wilson County, North Carolina, as described in the application, adjacent to the Raleigh-Durham Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (81 FR 32721, May 24, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby orders:

The application to reorganize FTZ 93 to expand the service area under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Dated: November 29, 2016.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29346 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2024]

Approval of Expansion of Subzone 122J; Valero Refining Company; Nueces County, Texas

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of subzones for specific uses;

Whereas, the Port of Corpus Christi Authority, grantee of Foreign-Trade Zone 122, has made application to the Board to expand Subzone 122J-Site 1 on behalf of Valero Refining Company to include an additional parcel in Corpus Christi, Texas (FTZ Docket B–59–2016, docketed September 12, 2016);

Whereas, notice inviting public comment has been given in the **Federal Register** (81 FR 64130, September 19, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's memorandum, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby approves the expansion of Subzone 122J on behalf of Valero Refining Company, as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.13.

Dated: November 29, 2016.

Paul Piquado

Assistant Secretary of Commerce for Enforcement and Compliance Alternate Chairman Foreign-Trade Zones Board.

[FR Doc. 2016–29343 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–83–2016]

Foreign-Trade Zone (FTZ) 24—Pittston, Pennsylvania; Notification of Proposed Production Activity; Brake Parts Inc; (Automotive Parts Kitting); Hazleton, Pennsylvania

Brake Parts Inc (BPI) submitted a notification of proposed production activity to the FTZ Board for its facility in Hazleton, Pennsylvania. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 30, 2016.

A separate application for subzone designation at the BPI facility was submitted and will be processed under Section 400.31 of the Board's regulations. The facility is used for the kitting of aftermarket automotive parts. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt BPI from customs duty payments on the foreign-status components used in export production. On its domestic sales, BPI would be able to choose the duty rates during customs entry procedures that apply to master cylinder kits, brake drum kits, brake pad kits, brake shoe kits and brake caliper kits (duty rate ranges from free to 2.5%) for the foreign-status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: Rubber O-

rings; rubber seals; rubber brake components; paperboard corrugated boxes; steel hex bolts; steel bolts; steel brake clips; galvanized cast iron brake brackets; master cylinders; brake drums; brake pads; brake shoes; and, wheel cylinders (duty rate ranges from free to 2.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 17, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

FOR FURTHER INFORMATION CONTACT: Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: December 1, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29351 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–169–2016]

Foreign-Trade Zone 24—Pittston, Pennsylvania; Application for Subzone; Brake Parts Inc.; Hazleton, Pennsylvania

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Eastern Distribution Center, Inc., grantee of FTZ 24, requesting subzone status for the facility of Brake Parts Inc., located in Hazleton, Pennsylvania. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on December 1, 2016.

The proposed subzone (28 acres) is located at 62 Green Mountain Road, Hazleton, Schuylkill County. A notification of proposed production activity has been submitted and will be published separately for public comment and processed under 15 CFR 400.37. The proposed subzone would be subject to the existing activation limit of FTZ 24.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 17, 2017. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 31, 2017.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: December 1, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29352 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–171–2016]

Foreign-Trade Zone 92—Gulfport, Mississippi; Application for Subzone; TopShip, LLC; Gulfport, Mississippi

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Mississippi Coast Foreign Trade Zone, Inc., grantee of FTZ 92, requesting subzone status for the facility of TopShip, LLC, located in Gulfport, Mississippi. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on December 1, 2016.

The proposed subzone (114.23 acres) is located at 13301 Seaway Road in Gulfport. The proposed subzone would be subject to the existing activation limit of FTZ 92. A notification of proposed production activity has been submitted and is being processed under 15 CFR 400.37 (Doc. B–57–2016).

In accordance with the Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 17, 2017. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 31, 2017.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: December 1, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29353 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2020]

Reorganization of Foreign-Trade Zone 20 (Expansion of Service Area) Under Alternative Site Framework; Norfolk, Virginia

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Virginia Port Authority, grantee of Foreign-Trade Zone 20, submitted an application to the Board (FTZ Docket B–31–2016, docketed May 9, 2016) for authority to expand the service area of the zone to include Elizabeth City, North Carolina and the Counties of Camden, Chowan, Currituck, Gates, Hertford, Pasquotank and Perquimans, North Carolina as described in the application, adjacent to the Norfolk-Newport News Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal**

Register (81 FR 29838, May 13, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 20 to expand the service area under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Dated: November 29, 2016.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29350 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2022]

Reorganization of Foreign-Trade Zone 244; (Expansion of Service Area) Under Alternative Site Framework; Riverside, California

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR Sec. 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the March Joint Powers Authority, grantee of Foreign-Trade Zone 244, submitted an application to the Board (FTZ Docket B–35–2016, docketed May 12, 2016, amended September 7, 2016) for authority to expand the service area of the zone to include a portion of the City of Lake Elsinore, California, as described in the application, adjacent to the Los Angeles/Long Beach U.S. Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (81 FR 31226, May 18, 2016) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby orders:

The amended application to reorganize FTZ 244 to expand the service area under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and to the Board's standard 2,000-acre activation limit for the zone.

Dated: November 29, 2016.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–29345 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF016

Schedules for Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops

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

ACTION: Notice of public workshops.

SUMMARY: Free Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops will be held in January, February, and March of 2017. Certain fishermen and shark dealers are required to attend a workshop to meet regulatory requirements and to maintain valid permits. Specifically, the Atlantic Shark Identification Workshop is mandatory for all federally permitted Atlantic shark dealers. The Protected Species Safe Handling, Release, and Identification Workshop is mandatory for vessel owners and operators who use bottom longline, pelagic longline, or gillnet gear, and who have also been issued shark or swordfish limited access permits. Additional free workshops will be conducted during 2017 and will be announced in a future notice.

DATES: The Atlantic Shark Identification Workshops will be held on January 12, February 9, and March 9, 2017.

The Protected Species Safe Handling, Release, and Identification Workshops will be held on January 17, January 20, February 1, February 3, March 7, and March 16, 2017.

See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The Atlantic Shark Identification Workshops will be held in Kenner, LA; Norfolk, VA; and Fort Pierce, FL.

The Protected Species Safe Handling, Release, and Identification Workshops will be held in Kenner, LA; Wilmington, NC; Port Saint Lucie, FL; Portsmouth, NH; Largo, FL; and Houston, TX.

See **SUPPLEMENTARY INFORMATION** for further details on workshop locations.

FOR FURTHER INFORMATION CONTACT: Rick Pearson by phone: (727) 824–5399, or by fax: (727) 824–5398.

SUPPLEMENTARY INFORMATION: The workshop schedules, registration information, and a list of frequently asked questions regarding these workshops are posted on the Internet at: *http://www.nmfs.noaa.gov/sfa/hms/compliance/workshops/index.html.*

Atlantic Shark Identification Workshops

Since January 1, 2008, Atlantic shark dealers have been prohibited from receiving, purchasing, trading, or bartering for Atlantic sharks unless a valid Atlantic Shark Identification Workshop certificate is on the premises of each business listed under the shark dealer permit that first receives Atlantic sharks (71 FR 58057; October 2, 2006). Dealers who attend and successfully complete a workshop are issued a certificate for each place of business that is permitted to receive sharks. These certificate(s) are valid for 3 years. Approximately 127 free Atlantic Shark Identification Workshops have been conducted since January 2007.

Currently, permitted dealers may send a proxy to an Atlantic Shark Identification Workshop. However, if a dealer opts to send a proxy, the dealer must designate a proxy for each place of business covered by the dealer's permit which first receives Atlantic sharks. Only one certificate will be issued to each proxy. A proxy must be a person who is currently employed by a place of business covered by the dealer's permit; is a primary participant in the identification, weighing, and/or first receipt of fish as they are offloaded from a vessel; and who fills out dealer reports. Atlantic shark dealers are prohibited from renewing a Federal shark dealer permit unless a valid Atlantic Shark Identification Workshop certificate for each business location that first receives Atlantic sharks has been submitted with the permit renewal

application. Additionally, trucks or other conveyances that are extensions of a dealer's place of business must possess a copy of a valid dealer or proxy Atlantic Shark Identification Workshop certificate.

Workshop Dates, Times, and Locations

1. January 12, 2017, 12 p.m.—4 p.m., DoubleTree Hotel, 2150 Veterans Memorial Highway, Kenner, LA 70062.
2. February 9, 2017, 12 p.m.—4 p.m. LaQuinta Inn, 1387 North Military Highway, Norfolk, VA 32502.
3. March 9, 2017, 12 p.m.—4 p.m. LaQuinta Inn, 2655 Crossroads Parkway, Fort Pierce, FL 34945.

Registration

To register for a scheduled Atlantic Shark Identification Workshop, please contact Eric Sander at *ericssharkguide@yahoo.com* or at (386) 852–8588.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items to the workshop:

- Atlantic shark dealer permit holders must bring proof that the attendee is an owner or agent of the business (such as articles of incorporation), a copy of the applicable permit, and proof of identification.
- Atlantic shark dealer proxies must bring documentation from the permitted dealer acknowledging that the proxy is attending the workshop on behalf of the permitted Atlantic shark dealer for a specific business location, a copy of the appropriate valid permit, and proof of identification.

Workshop Objectives

The Atlantic Shark Identification Workshops are designed to reduce the number of unknown and improperly identified sharks reported in the dealer reporting form and increase the accuracy of species-specific dealer-reported information. Reducing the number of unknown and improperly identified sharks will improve quota monitoring and the data used in stock assessments. These workshops will train shark dealer permit holders or their proxies to properly identify Atlantic shark carcasses.

Protected Species Safe Handling, Release, and Identification Workshops

Since January 1, 2007, shark limited-access and swordfish limited-access permit holders who fish with longline or gillnet gear have been required to submit a copy of their Protected Species Safe Handling, Release, and Identification Workshop certificate in order to renew either permit (71 FR 58057; October 2, 2006). These certificate(s) are valid for 3 years. As such, vessel owners who have not already attended a workshop and received a NMFS certificate, or vessel owners whose certificate(s) will expire prior to the next permit renewal, must attend a workshop to fish with, or renew, their swordfish and shark limited-access permits. Additionally, new shark and swordfish limited-access permit applicants who intend to fish with longline or gillnet gear must attend a Protected Species Safe Handling, Release, and Identification Workshop and submit a copy of their workshop certificate before either of the permits will be issued. Approximately 244 free Protected Species Safe Handling, Release, and Identification Workshops have been conducted since 2006.

In addition to certifying vessel owners, at least one operator on board vessels issued a limited-access swordfish or shark permit that uses longline or gillnet gear is required to attend a Protected Species Safe Handling, Release, and Identification Workshop and receive a certificate. Vessels that have been issued a limited-access swordfish or shark permit and that use longline or gillnet gear may not fish unless both the vessel owner and operator have valid workshop certificates onboard at all times. Vessel operators who have not already attended a workshop and received a NMFS certificate, or vessel operators whose certificate(s) will expire prior to their next fishing trip, must attend a workshop to operate a vessel with swordfish and shark limited-access permits that uses longline or gillnet gear.

Workshop Dates, Times, and Locations

1. January 17, 2017, 9 a.m.–5 p.m., Hilton Hotel, 901 Airline Drive, Kenner, LA 70062.

2. January 20, 2017, 9 a.m.–5 p.m., Hilton Garden Inn, 6745 Rock Spring Road, Wilmington, NC 28405.

3. February 1, 2017, 9 a.m.–5 p.m., Holiday Inn, 10120 South Federal Highway, Port St Lucie, FL 34952.

4. February 3, 2017, 9 a.m.–5 p.m., Holiday Inn, 300 Woodbury Avenue, Portsmouth, NH 03801.

5. March 7, 2017, 9 a.m.–5 p.m., Holiday Inn, 210 Seminole Boulevard, Largo, FL 33770.

6. March 16, 2017, 9 a.m.–5 p.m., Holiday Inn Express, 8080 Main Street, Houston, TX 77025.

Registration

To register for a scheduled Protected Species Safe Handling, Release, and Identification Workshop, please contact Angler Conservation Education at (386) 682–0158.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items with them to the workshop:

- Individual vessel owners must bring a copy of the appropriate swordfish and/or shark permit(s), a copy of the vessel registration or documentation, and proof of identification.
- Representatives of a business-owned or co-owned vessel must bring proof that the individual is an agent of the business (such as articles of incorporation), a copy of the applicable swordfish and/or shark permit(s), and proof of identification.
- Vessel operators must bring proof of identification.

Workshop Objectives

The Protected Species Safe Handling, Release, and Identification Workshops are designed to teach longline and gillnet fishermen the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, and smalltooth sawfish. In an effort to improve reporting, the proper identification of protected species will also be taught at these workshops. Additionally, individuals attending these workshops will gain a better understanding of the requirements for participating in these fisheries. The overall goal of these workshops is to provide participants with the skills needed to reduce the mortality of protected species, which may prevent additional regulations on these fisheries in the future.

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

Dated: December 2, 2016.

Emily H. Menashes,

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

[FR Doc. 2016–29323 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

First Responder Network Authority Combined Committee and Board Meeting

AGENCY: First Responder Network Authority (FirstNet), U.S. Department of Commerce.

ACTION: Notice of public meeting of the First Responder Network Authority Board.

SUMMARY: The Board of the First Responder Network Authority (Board) will convene an open public meeting on December 14, 2016, preceded by open public meetings of the Board Committees on December 13, 2016.

DATES: A joint meeting of the four FirstNet Board Committees will be held on December 13, 2016, between 8:00 a.m. and 3:30 p.m. (PST). The meeting of the Governance and Personnel, Technology, Consultation and Outreach, and Finance Committees will be open to the public from 8:00 a.m. to 10:15 a.m. (PST). The FirstNet Committees will be in a closed session from 10:15 a.m. to 3:30 p.m. (PST). The FirstNet Board will hold an open public meeting on December 14, 2016 between 8:00 a.m. and 9:55 a.m. (PST) and between 10:20 a.m. and 11:00 a.m. (PST). The FirstNet Board will be in closed session on December 14, 2016 between 9:55 a.m. and 10:20 a.m. (PST).

ADDRESSES: The meetings on December 13 and December 14, 2016 will be held at the Doubletree by Hilton Hotel Sacramento, 2001 Point West Way, Sacramento, CA 95815. Members of the public may listen to the meeting by dialing toll free 1–888–324–8109 and entering participant code 2827944#.

FOR FURTHER INFORMATION CONTACT: Karen Miller-Kuwana, Board Secretary, FirstNet, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192; telephone: (571) 665–6177; email: *Karen.Miller-Kuwana@firstnet.gov.* Please direct media inquiries to Ryan Oremland at (571) 665–6186.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Board of the First Responder Network Authority (Board) will convene an open public meeting on December 14, 2016, preceded by open public meetings of the Board Committees on December 13, 2016.

Background: The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Title VI, 126 Stat. 256 (codified at 47 U.S.C. 1401 *et seq.*)) (Act) established FirstNet as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs FirstNet to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Board is responsible for making strategic decisions regarding FirstNet's operations. The FirstNet Board held its first public meeting on September 25, 2012.

Matters to be Considered: FirstNet will post a detailed agenda for the Combined Committee and Board Meetings on its Web site, *http://www.firstnet.gov,* prior to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the Committees and the Board may involve commercial or financial information that is privileged or confidential or other legal matters affecting FirstNet. As such, the Committee Chairs and Board Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

Times and Dates of Meeting: A joint meeting of the four FirstNet Board Committees will be held on December 13, 2016, between 8:00 a.m. and 3:30 p.m. (PST). The meeting of the Governance and Personnel, Technology, Consultation and Outreach, and Finance Committees will be open to the public from 8:00 a.m. to 10:15 a.m. (PST). The FirstNet Committees will be in a closed session from 10:15 a.m. to 3:30 p.m. (PST). The FirstNet Board will hold an open public meeting on December 14, 2016 between 8:00 a.m. and 9:55 a.m. (PST) and between 10:20 a.m. and 11:00 a.m. (PST). The FirstNet Board will be in closed session on December 14, 2016 between 9:55 a.m. and 10:20 a.m. (PST). The times listed above are subject to change. Please refer to FirstNet's Web site at *www.firstnet.gov* for the most up-to-date information.

Place: The meetings on December 13 and December 14, 2016 will be held at the Doubletree by Hilton Hotel Sacramento, 2001 Point West Way, Sacramento, CA 95815. Members of the public may listen to the meeting by dialing toll free 1–888–324–8109 and entering participant code 2827944#.

Other Information: These meetings are open to the public and press on a first-come, first-served basis. Space is limited. To ensure an accurate headcount, all expected attendees are asked to provide notice of intent to attend by sending an email to *BoardRSVP@firstnet.gov.* If the number of RSVPs indicates that expected attendance has reached its capacity, FirstNet will respond to all subsequent notices indicating that capacity has been reached and that in-person viewing may no longer be available but that the meeting may still be viewed by webcast as detailed below. For access to the meetings, valid government issued photo identification may be requested for security reasons.

The Combined Committee and Board Meetings are accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Ms. Miller-Kuwana by telephone (571) 665–6177 or email at *Karen.Miller-Kuwana@firstnet.gov* at least five (5) business days before the applicable meeting.

The meeting will also be webcast. Please refer to FirstNet's Web site at *www.firstnet.gov* for webcast instructions and other information. Viewers experiencing any issues with the live webcast may email *support@sparkstreetdigital.com* or call 202–684–3361 x3 for support. A variety of automated troubleshooting tests are also available via the ''Troubleshooting Tips'' button on the webcast player. The meetings will also be available to interested parties by phone. To be connected to the meetings in listen-only mode by telephone, please dial toll free 1–888–324–8109 and enter participant code 2827944#. If you experience technical difficulty, please contact the Conferencing Center customer service at 1–866–900–1011.

Records: FirstNet maintains records of all Board proceedings. Minutes of the Board Meeting and the Committee meetings will be available at *www.firstnet.gov.*

Dated: December 1, 2016.

Karen Miller-Kuwana,

Board Secretary, First Responder Network Authority.

[FR Doc. 2016–29302 Filed 12–6–16; 8:45 am]

BILLING CODE 3510–TL–P

DEPARTMENT OF DEFENSE

Department of the Air Force

U.S. Air Force Scientific Advisory Board Notice of Meeting

AGENCY: Department of the Air Force, Air Force Scientific Advisory Board.

ACTION: Federal Registrar meeting notice.

SUMMARY: The United States Air Force Scientific Advisory Board plans to hold its Winter Board meeting in January.

Portions of this meeting will be open to the public.

DATES: The meeting date is January 24, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will take place at the Beckman Center of National Academies of Science and Engineering, 100 Academy Drive, Irvine, California 92617.

FOR FURTHER INFORMATION CONTACT: The Scientific Advisory Board meeting organizer, Major Mike Rigoni at *michael.j.rigoni.mil@mail.mil* or 240–612–5506, United States Air Force Scientific Advisory Board, 1500 West Perimeter Road, Ste. #3300, Joint Base Andrews, MD 20762.

SUPPLEMENTARY INFORMATION: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense announces the United States Air Force (USAF) Scientific Advisory Board (SAB) Winter Board meeting will take place on 24 January 2017 at the Beckman Center of National Academies of Science and Engineering, located at 100 Academy Drive, Irvine, California 92617. The meeting will occur from 8:00 a.m.–5:00 p.m. on Tuesday, 24 January 2017. The session that will be open to the *general public* will be held from 8:00 a.m. to 8:30 a.m. on 24 January 2017. In accordance with 5 U.S.C. 552b, as amended, and 41 CFR 102–3.155, a number of sessions of the Air Force Scientific Advisory Board Winter Board meeting will be closed to the general public because they will discuss classified information and matters covered by Section 552b of Title 5, United States Code, subsection (c), subparagraph (1).

Any member of the public that wishes to attend this meeting or provide input to the Air Force Scientific Advisory Board must contact the Scientific Advisory Board meeting organizer at the phone number or email address listed in this announcement at least five working days prior to the meeting date. Please ensure that you submit your written statement in accordance with 41 CFR 102–3.140(c) and section 10(a)(3) of the Federal Advisory Committee Act. Statements being submitted in response to the agenda mentioned in this notice must be received by the Scientific Advisory Board meeting organizer at least five calendar days prior to the meeting commencement date. The Scientific Advisory Board meeting organizer will review all timely submissions and respond to them prior to the start of the meeting identified in this notice. Written statements received after this date may not be considered by the Scientific Advisory Board until the next scheduled meeting.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2016–29102 Filed 12–6–16; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2016–OS–0114]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Notice to delete a System of Records.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular No. A–130, notice is hereby given that the Department of Defense proposes to delete a system of records, ''International Affairs Personnel Initiatives Database,'' last published at 75 FR 19622 on April 15, 2010. This system of records is a single central facility with the Department of Defense (DoD) that maintains and verifies information provided by individuals seeking international affairs certification based on their current experience and training.

Based on a recent review of DSCA 01, International Affairs Personnel Initiatives Database, it has been determined that this system of records is covered by system of records notice DSCA 07, Security Assistance Network (SAN) (September 22, 2016, 81 FR 65343). All records will be maintained in accordance with the DSCA 07 records retention. Therefore, DSCA 01, International Affairs Personnel Initiatives Database can be deleted.

DATES: Comments will be accepted on or before January 6, 2017. This proposed action will be effective the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mrs. Luz D. Ortiz, Chief, Records, Privacy and Declassification Division (RPD2), 1155 Defense Pentagon, Washington, DC 20301–1155, or by phone at (571) 372–0478.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties, and Transparency Division Web site at *http://dpcld.defense.gov/.*

Dated: December 2, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DELETION:

DSCA 01

International Affairs Personnel Initiatives Database (April 15, 2010, 75 FR 19622)

Reason: Based on a recent review of DSCA 01, International Affairs Personnel Initiatives Database, it has been determined that this system of records is covered by system of records notice DSCA 07, Security Assistance Network (SAN) (September 22, 2016, 81 FR 65343). All records will be maintained in accordance with the DSCA 07 records retention. Therefore, DSCA 01, International Affairs Personnel Initiatives Database can be deleted.

[FR Doc. 2016–29304 Filed 12–6–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0137]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Middle Grades Longitudinal Study of 2017–18 (MGLS: 2017) Operational Field Test (OFT) and Recruitment for Main Study Base-Year Study

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 6, 2017.

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–2016–ICCD–0137. 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, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Middle Grades Longitudinal Study of 2017–18 (MGLS: 2017) Operational Field Test (OFT) and Recruitment for Main Study Base-year Study.

OMB Control Number: 1850–0911.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 34,952.

Total Estimated Number of Annual Burden Hours: 17,391.

Abstract: The Middle Grades Longitudinal Study of 2017–18 (MGLS:2017) is the first study conducted by the National Center for Education Statistics (NCES) to follow a nationally-representative sample of students as they enter and move through the middle grades (grades 6–8). The data collected through repeated measures of key constructs will provide a rich descriptive picture of the academic experiences and development of students during these critical years and will allow researchers to examine associations between contextual factors and student outcomes. The study will focus on student achievement in mathematics and literacy along with measures of student socioemotional wellbeing and other outcomes. The study will also include a special sample of students with different types of disabilities that will provide descriptive information on their outcomes, educational experiences, and special education services. Main Study Base-year data for the MGLS:2017 will be collected from a nationally-representative sample of 6th grade students beginning in January 2018, with annual follow-ups beginning in January 2019 and in January 2020 when most of the students in the sample will be in grades 7 and 8, respectively. In preparation for the national data collection, referred to as the Main Study, the data collection instruments and procedures must be field tested. An Item Validation Field Test (IVFT) was conducted in the winter/spring 2016 to determine the psychometric properties of items and the predictive potential of assessment and survey items so that valid, reliable, and useful assessment and survey instruments can be composed for the Main Study. An Operational Field Test (OFT) will begin in January 2017 to test the near final instruments and the recruitment and data collection processes and procedures in preparation for the Main Study. OMB approved the recruitment of schools, school districts, and parents to participate in the OFT in December 2015 with the latest change request approved in March 2016 (OMB# 1850–0911 v.6,9,10). The request to conduct the OFT data collection, Main Study recruitment, and tracking of OFT students is currently under review at OMB (OMB# 1850–0911 v.11), with expected approval in early December 2016. This request is to modify language in the parent contacting materials, the video introductory script for the student session, and the study questionnaires (student, parent, math teacher, special education teacher, school administrator, and facilities observation checklist). These changes are driven by the recently completed analyses of IVFT results. The data collection for the OFT will begin January 23, 2017. Main Study recruitment will also commence in January 2017.

Dated: December 2, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–29327 Filed 12–6–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information: Personnel Development to Improve Services and Results for Children with Disabilities—Preparation of Special Education, Early

Intervention, and Related Services Leadership Personnel

Notice inviting applications for a new award for fiscal year (FY) 2017.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.325D.

DATES: *Applications Available:* December 7, 2016.

Deadline for Transmittal of Applications: February 6, 2017.

Deadline for Intergovernmental Review: April 6, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, early intervention, related services, and regular education to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1462 and 20 U.S.C. 1481).

Absolute Priority: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel.

Background: The purpose of the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel priority is to support existing doctoral degree programs that prepare special education, early intervention, and related services personnel who are well-qualified for, and can act effectively in, leadership positions as researchers and special education/early intervention/related services personnel preparers in institutions of higher education (IHEs), or as leaders in national organizations, State educational agencies (SEAs), lead agencies (LAs), local educational agencies (LEAs), early intervention services programs (EIS programs), or schools.

There is a well-documented need for leadership personnel to fill faculty and leadership positions in special education, early intervention, and related services (Castillo, Curtis, & Tan, 2014; Montrosse & Young, 2012; Robb, Smith, & Montrosse, 2012; Smith, Montrosse, Robb, Tyler, & Young, 2011; Smith, Robb, West, & Tyler, 2010; Woods & Snyder, 2009). These leaders conduct research to increase the knowledge of effective interventions and services for children and youth with disabilities. These leaders also teach practices supported by evidence to future special education, early intervention, and related services professionals who will work in a variety of educational settings and provide services directly to these children (Robb et al., 2012; Smith et al., 2010; West & Hardman, 2012). Shortages in these leadership positions could limit the field's capacity to generate new knowledge of effective interventions and to prepare future professionals to improve outcomes for children with disabilities (Smith et al., 2011).

Shortages of leadership personnel at State and local agencies to fill special education and early intervention administrator positions have also been noted (Billingsley, Crockett, & Kamman, 2014). These administrators supervise and evaluate the implementation of instructional programs supported by evidence to make sure that State or local agencies are meeting the needs of children with disabilities. Administrators also ensure that schools and programs meet Federal, State, and local requirements for special education, early intervention, and related services (Lashley & Boscardin, 2003).

Federal support can increase the supply of personnel who have the necessary knowledge and skills to assume leadership positions in special education, early intervention, and related services as researchers and special education/early intervention/related services personnel preparers in IHEs, or as leaders in national organizations, SEAs, LAs, LEAs, EIS programs, or schools. Critical competencies for special education, early intervention, and related services personnel vary depending on the type of personnel and the requirements of the preparation program but can include, for example, skills needed for postsecondary instruction, administration, policy development, professional practice, leadership, or research. However, all leadership personnel need to have current knowledge of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities.[1]

Priority: The purpose of the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel priority is to support pre-existing doctoral degree programs that prepare special education, early intervention, and related services personnel who are well-qualified for, and can act effectively in, leadership positions as researchers and special education/early intervention/related services personnel preparers in IHEs, or as leaders in national organizations, SEAs, LAs, LEAs, or EIS programs. This priority supports two types of programs:

Type A programs are designed to prepare special education, early intervention, and related services personnel as researchers and personnel preparers in IHEs. Type A programs culminate in a doctoral degree.

Note: Preparation programs that lead to clinical doctoral degrees in related services (*e.g.,* a Doctor of Audiology degree or Doctor of Physical Therapy degree) are not included in this priority. These types of preparation programs are eligible to apply for funding under the Personnel Preparation in Special Education, Early Intervention, and Related Services priority (CFDA 84.325K) that the Office of Special Education Programs (OSEP) intends to fund in FY 2017.

Type B programs are designed to prepare special education or early intervention administrators to work as leaders in national organizations, SEAs, LAs, LEAs, or EIS programs. Type B programs prepare personnel for positions such as SEA special education administrators, LEA or regional special education directors, school-based special education directors, including those in youth correctional facilities, preschool coordinators, and early intervention coordinators. Type B programs culminate in a doctoral degree.

Note: The preparation of school principals is not included in this priority.

Note: Applicants must identify the specific program type, A or B, for which they are applying for funding as part of the abstract. Applicants may not submit the same proposal for more than one program type.

To be considered for funding under the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel absolute priority, all program applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the

[1] For a definition of ''high-need children with disabilities,'' please see footnote 2.

programmatic and administrative requirements specified in the priority.

The requirements of this priority are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how—

(1) The project addresses national, State, regional, or district needs for leadership personnel to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities.[2] To address this requirement, the applicant must—

(i) Present appropriate and applicable data (*e.g.,* national, State) demonstrating the need for the leadership personnel the applicant proposes to prepare; and

(ii) Present data demonstrating the effectiveness of the doctoral program to date in producing leaders in special education, early intervention, or related services such as: the professional accomplishments of program graduates (*e.g.,* public service, honors, or publications) that demonstrate their leadership in special education, early intervention, or related services; the effectiveness of program graduates as educators of teachers, service providers, or administrators, including any results from evaluating the impact of those teachers, service providers, or administrators on the outcomes of children with disabilities; the average amount of time it takes for program graduates to complete the program; the number of program graduates; and the percentage of program graduates finding employment directly related to their preparation.

Note: Data on the effectiveness of a doctoral program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (*i.e.,* the total number of scholars or program graduates) must be provided.

(2) Scholar competencies to be acquired in the program relate to knowledge and skills needed by the leadership personnel the applicant proposes to prepare, including knowledge of technologies designed to provide instruction. To address this requirement, the applicant must—

(i) Identify the competencies needed by leadership personnel in postsecondary instruction, administration, policy development, professional practice, leadership, or research in order to administer programs or provide, or prepare others to provide, interventions and services that improve outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities; and

(ii) Provide the conceptual framework of the leadership preparation program, including any empirical support, that will promote the acquisition of the identified competencies needed by leadership personnel, including knowledge of technologies designed to provide instruction, and, where applicable, how these competencies relate to the project's specialized preparation area.

(b) Demonstrate, in the narrative section of the application under ''Quality of the Project Services,'' how—

(1) The applicant will recruit and support high-quality scholars. The narrative must—

(i) Describe the selection criteria the applicant will use to identify high-quality applicants for admission in the program;

(ii) Describe the recruitment strategies the applicant will use to attract high-quality applicants and any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, including individuals with disabilities; and

(iii) Describe the approach the applicant will use to help all scholars, including individuals with disabilities, complete the program; and

(2) The project is designed to promote the acquisition of the competencies needed by leadership personnel to administer programs or provide, or prepare others to provide, interventions and services supported by evidence to improve outcomes, including college- and career-readiness of children with disabilities. To address this requirement, the applicant must—

(i) Describe how the components of the project, such as coursework, internship or practicum experiences, research requirements, and other opportunities provided to scholars to analyze data, critique research and methodologies, and practice newly acquired knowledge and skills, will enable the scholars to acquire the competencies needed by leadership personnel for postsecondary instruction, administration, policy development, professional practice, leadership, or research in special education, early intervention, or related services;

(ii) Describe how the components of the project are integrated in order to support the acquisition and enhancement of the identified competencies needed by leadership personnel in special education, early intervention, or related services, including knowledge of technologies designed to provide instruction;

(iii) Describe how the components of the project prepare scholars to administer programs or provide, or prepare others to provide, interventions and services that are supported by evidence to improve outcomes, including college- and career-readiness, of children with disabilities in a variety of settings, including in high-need LEAs;[3] high-poverty schools;[4] low-performing schools;[5] priority schools (in the case of States that have received the Department of Education's (Department's) approval of a request for ESEA flexibility);[6] and early childhood programs located within the geographical boundaries of a high-need LEA;

(iv) Demonstrate, through a letter of support from a partnering agency, school, or program, that there is an agreement with one or more high-need LEAs; publicly funded preschool programs, including Head Start programs, located within the geographic boundaries of a high-need LEA; or programs serving children eligible for services under Part C or Part B, section 619 of IDEA located within the

[2] For purposes of this priority, ''high-need children with disabilities'' refers to children (ages birth through 21, depending on the State) who are eligible for services under IDEA, and who may be further disadvantaged and at risk of educational failure because they: (1) Are living in poverty, (2) are far below grade level, (3) are at risk of not graduating with a regular high school diploma on time, (4) are homeless, (5) are in foster care, (6) have been incarcerated, (7) are English learners, (8) are pregnant or parenting teenagers, (9) are new immigrants, (10) are migrant, or (11) are not on track to being college- or career-ready by graduation.

[3] For the purposes of this priority, the term ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

[4] For the purposes of this priority, the term ''high-poverty school'' means a school that is in the highest two quartiles of schools served by an LEA, based on the percentage of enrolled students from low-income families as defined in section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA).

[5] For the purposes of this priority, the term ''low-performing school'' means a school receiving assistance through Title I of the ESEA that, at the time of submission of an application under this competition, is (1) identified as a school in need of corrective action or restructuring under section 1116 of the ESEA, as amended by the No Child Left Behind Act of 2001 (NCLB); or (2) identified as a priority or focus school in a State that implemented ESEA flexibility. The inclusion of these schools as ''low-performing schools'' reflects the fact that the 2016–2017 school year is a year of transition between requirements of the ESEA as amended by the NCLB and the ESEA as amended by the Every Student Succeeds Act.

[6] For the purposes of this priority, the term ''priority school'' means a school that has been identified by the State as a priority school pursuant to the State's approved request for ESEA flexibility.

geographic boundaries of a high-need LEA, that it will provide scholars with a high-quality internship or practicum experience in a school in a high-need LEA, publicly funded preschool, or early intervention program;

(v) Describe how the project will use resources, as appropriate, available through technical assistance centers, which may include centers funded by the Department; and

(vi) Describe the approach that faculty members will use to mentor scholars with the goal of helping them acquire competencies needed by leadership personnel and promote career goals in special education, early intervention, or related services.

(c) Demonstrate, in the narrative section of the application under ''Quality of the Project Evaluation,'' how—

(1) The applicant will evaluate how well the goals or objectives of the proposed leadership project have been met. The applicant must describe the outcomes to be measured for both the project and the scholars, particularly the acquisition of scholar competencies and their impact on the services provided by future teachers, service providers, or administrators; and the evaluation methodologies to be employed, including proposed instruments, data collection methods, and possible analyses;

(2) The applicant will collect, analyze, and use data on current scholars and scholars who graduate from the program to improve the proposed program on an ongoing basis; and

(3) The applicant will report the evaluation results to OSEP in its annual and final performance reports.

(d) Demonstrate, in the narrative under ''Required Project Assurances,'' or appendices as directed, that the following program requirements are met. The applicant must—

(1) Include in the application appendix—

(i) Course syllabi for all coursework in the major and any required coursework for a minor;

(ii) Course syllabi for all research methods, evaluation methods, or data analysis courses required by the degree program and elective research methods, evaluation methods, or data analysis courses that have been completed by more than one scholar enrolled in the program in the last five years; and

(iii) For new coursework, proposed syllabi;

Note: Applicants for Type B programs should provide a syllabus or syllabi for current or proposed courses that provide instruction on, or permit practice with, research and the methodological, statistical, and practical considerations in the use of data on early learning outcomes, student achievement, or growth in student achievement to evaluate the effectiveness of early intervention providers, related services providers, teachers, or principals.

(2) Ensure that the proposed number of scholars to be recruited into the program can graduate from the program by the end of the grant's project period. The described scholar recruitment strategies, including recruitment of individuals with disabilities, the program components and their sequence, and proposed budget must be consistent with this project requirement;

(3) Ensure scholars will not be selected based on race or national origin/ethnicity. Per the Supreme Court's decision in *Adarand Constructors, Inc.* v. *Pena,* 515 U.S. 200 (1995), the Department does not allow the selection of individuals on the basis of race or national origin/ethnicity. For this reason, grantees must ensure that any discussion of the recruitment of scholars based on race or national origin/ethnicity distinguishes between increasing the pool of applicants and actually selecting scholars;

(4) Ensure that the project will meet the requirements in 34 CFR 304.23, particularly those related to informing all scholarship recipients of their service obligation commitment. Failure by a grantee to properly meet these requirements is a violation of the grant award that may result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, the grantee must prepare, and ensure that each scholarship recipient signs, the following two documents:

(i) A Pre-Scholarship Agreement prior to the scholar receiving a scholarship for an eligible program (Office of Management and Budget (OMB) Control Number 1820–0686); and

(ii) An Exit Certification immediately upon the scholar leaving, completing, or otherwise exiting that program (OMB Control Number 1820–0686);

(5) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars proposed in the application and before transferring a scholar to another preparation program funded by OSEP;

(6) Ensure that the project will meet the statutory requirements in section 662(e) through 662(h) of IDEA;

(7) Ensure that at least 65 percent of the total requested budget over the five years will be used for scholar support;

(8) Ensure that the IHE will not require scholars enrolled in the program to work (*e.g.,* as graduate assistants) as a condition of receiving support (*e.g.,* tuition, stipends) from the proposed project, unless the work is specifically related to the acquisition of scholars' competencies and the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA;

(9) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC, during each year of the project. The budget may also provide for the attendance of scholars at the same three-day project directors' meetings in Washington, DC;

(10) Ensure that if the project maintains a Web site, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility;

(11) Ensure that scholar accomplishments (*e.g.,* publications, awards) will be reported in annual and final performance reports; and

(12) Ensure that annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under the Government Performance and Results Act of 1993 (GPRA). Applicants are encouraged to visit the Personnel Development Program Data Collection System (DCS) Web site at *https://pdp.ed.gov/osep* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant, although grantees may submit data as needed, year round. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590). Data collection includes the submission of a signed, completed Pre-Scholarship Agreement and Exit Certification for each scholar funded under an OSEP grant (see paragraph (4) of this section, subparagraphs (i) and (ii)).

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Lashley, C., & Boscardin, M. L. (2003). *Special education administration at the crossroads: Availability, licensure, and preparation of special education administrators.* Gainesville, FL: Center on Personnel Studies in Special Education, University of Florida. Retrieved from *www.coe.ufl.edu/copsse/docs/IB-8/1/IB-8.pdf.*

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West, J. E., & Hardman, H. L. (2012). Averting current and future special education faculty shortages: Policy implications and recommendations. *Teacher Education and Special Education, 35,* 154–160.

Woods, J., & Snyder, P. (2009). Interdisciplinary doctoral leadership training in early intervention. *Infants & Young Children, 22*(1), 32–34.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $83,700,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2017, of which we intend to use an estimated $3,250,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2018 from the list of unfunded applications from this competition.

Estimated Range of Awards: $225,000–$250,000 per year.

Estimated Average Size of Awards: $237,500 per year.

Maximum Award: We will reject any application that proposes a budget exceeding $250,000 for a single budget period of 12 months.

Estimated Number of Awards: 13.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, private nonprofit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Eligible Subgrantees:* (a) Under 34 CFR 75.708(b) and (c) a grantee may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application.

(b) The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements:*

(a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant for, and recipient of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this competition as follows: CFDA number 84.325D.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier

New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit and double-spacing requirements do not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the page limit and double-spacing requirements do apply to all of Part III, the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

We will reject your application if you exceed the page limit in the application narrative section, or if you apply standards other than those specified in this notice and the application package.

3. *Submission Dates and Times:* Applications Available: December 7, 2016.

Deadline for Transmittal of Applications: February 6, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: April 6, 2017.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.* Applications for grants under the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel competition, CFDA number 84.325D, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel competition at *www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.325, not 84.325D).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully

uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.

• You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov*. In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html*.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF. Additional, detailed information on how to attach files is in the application instructions.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the *Grants.gov* system;

and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal

holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Celia Rosenquist, U.S. Department of Education, 400 Maryland Avenue SW., Room 5146, Potomac Center Plaza (PCP), Washington, DC 20202–5076. FAX: (202) 245–7590.

Your paper application must be submitted in accordance with the mail or hand-delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.* If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325D), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.* If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325D), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements

in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under GPRA, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include: (1) The percentage of preparation programs that incorporate scientifically or evidence-based practices into their curricula; (2) the percentage of scholars completing preparation programs who are knowledgeable and skilled in evidence-based practices for children with disabilities; (3) the percentage of scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of scholars completing preparation programs who are working in the area(s) in which they were prepared upon program completion; and (5) the Federal cost per scholar who completed the preparation program.

In addition, the Department will gather information on the following outcome measures: (1) The percentage of scholars who completed the preparation program and are employed in high-need districts; (2) the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years; and (3) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Celia Rosenquist, U.S. Department of Education, 400 Maryland Avenue SW., Room 5146, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7373.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: December 2, 2016.

Sue Swenson,

Deputy Assistant Secretary for Special Education and Rehabilitative Services, delegated the authority to perform the functions and duties of the Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2016–29371 Filed 12–6–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Training and Information for Parents of Children With Disabilities—Community Parent Resource Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information

Training and Information for Parents of Children with Disabilities—Community Parent Resource Centers Notice inviting applications for new awards for fiscal year (FY) 2017.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.328C.

DATES:

Applications Available: December 7, 2016.

Deadline for Transmittal of Applications: February 6, 2017.

Deadline for Intergovernmental Review: April 6, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to ensure that parents of children with disabilities receive training and information to help improve results for their children.

Priority: In accordance with 34 CFR 75.105(b)(2)(iv) and (v), this priority is from allowable activities specified in the statute, or otherwise authorized in the statute (see sections 672 and 681(d) of the Individuals with Disabilities Education Act (IDEA)).

Absolute Priority: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Community Parent Resource Centers

Background: The purpose of this priority is to fund seven Community Parent Resource Centers (CPRCs) designed to meet the specific needs of parents of children with disabilities, and youth with disabilities, who experience significant isolation from available sources of information and support in the geographically defined communities served by the centers. These parents can include, for example, low-income parents, parents with limited English proficiency, and parents with disabilities. Youth can include, for example, youth living in low-income households and youth with limited English proficiency.

More than 35 years of research and experience has demonstrated that the education of children with disabilities can be made more effective by strengthening the ability of parents to participate fully in the education of their children at school and at home (see section 601(c)(5)(B) of IDEA). Since the Department first funded CPRCs over 20 years ago, the CPRC program has helped parents in their communities set high expectations for children with disabilities and has provided parents with the information and training they need to help their children meet those expectations. Information about the Office of Special Education's parent training and information program can be found at: *www.parentcenterhub.org.*

CPRCs, consistent with section 672(b) of IDEA, help families in the geographically defined communities identified by the applicant: (a) Navigate systems that provide early intervention, special education, general education, postsecondary options, and related services; (b) understand the nature of their children's disabilities; (c) learn about their rights and responsibilities under IDEA; (d) expand their knowledge of evidence-based, as defined in this notice, education practices to help their children succeed; (e) strengthen their collaboration with professionals; (f) locate resources available for themselves and their children, which connects them to their local communities; and (g) advocate for improved student achievement, increased graduation rates, and improved postsecondary outcomes for all children through participation in school reform activities. In addition, CPRCs may help youth with disabilities in their communities have high expectations for themselves and understand their rights and responsibilities. In addition, effective CPRCs can partner with local agencies, providing expertise on how to better support families in their communities and help them access other community supports that empower families.

The CPRCs to be funded through this priority will provide parents with information, individual assistance, and training to enable them to: (a) Advocate for their children's access to appropriate services, including access to general education classrooms and extracurricular activities; (b) help their children meet developmental and academic goals; (c) help their children meet challenging expectations established for all children; and (d) prepare their children to achieve positive postsecondary outcomes that lead to lives that are as productive and independent as possible. In addition, all CPRCs will be required to help youth with disabilities become effective self-advocates.

Priority: At a minimum, the CPRCs must: (1) Increase parents' capacity to help their children with disabilities improve their early learning, school-aged, and postsecondary outcomes; and (2) increase youth with disabilities' capacity to be effective self-advocates. To be considered for funding under this priority, an applicant must meet the application, programmatic, and administrative requirements of this priority. Applicants must—

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how the proposed project will—

(1) Address the needs of parents of children with disabilities who experience significant isolation from available sources of information and support for services that increase the parents' capacity to help their children improve their early learning, school-aged, and postsecondary outcomes. To meet this requirement, the applicant must—

(i) Present appropriate information on the characteristics and needs of parents in the identified community who experience significant challenges identifying reliable sources of information and support, including, for example, low-income parents, parents with limited English proficiency, parents of incarcerated youth with disabilities, and parents with disabilities;

(ii) Present appropriate information about the identified community, including a description of its geographic area, population demographics, and the resources available in the community to support all families;

(iii) Demonstrate knowledge of best practices in providing training and information to parents and youth in the identified community;

(iv) Demonstrate knowledge of current evidence-based education practices and policy initiatives to improve outcomes in early intervention and early childhood, general and special education, transition services, and postsecondary options, including, if applicable to its community, the Promoting the Readiness of Minors in Supplemental Security Income (PROMISE) initiative; and

(v) Demonstrate knowledge of how to identify and work with appropriate partners in the community, including agencies providing Part C services under IDEA; local educational agencies (LEAs); child welfare agencies; disability-specific resources serving families, such as local service providers; and other community nonprofits serving families; and

(2) Address the needs of youth with disabilities for services that increase their capacity to be effective self-advocates. To meet this requirement, the applicant must—

(i) Present appropriate information on the needs of youth with disabilities in the identified community who experience significant isolation from available sources of information and support, including, for example, youth who are low-income, homeless, or limited English proficient, have dropped out of school, or are in foster care or involved in the juvenile justice system;

(ii) Demonstrate knowledge of best practices in providing training and information to youth with disabilities in the identified community;

(iii) Demonstrate knowledge of best practices in self-advocacy; and

(iv) Demonstrate knowledge of how to work with appropriate partners serving youth with disabilities in the identified community, including local agencies, other nonprofits, and Independent Living Centers that provide assistance such as postsecondary education options, employment training, and supports.

(b) Demonstrate, in the narrative section of the application, under ''Quality of the Project Services,'' how the proposed project will—

(1) Use a project logic model (see paragraph (f)(1) of this priority) to guide the development of project plans and activities within the identified community;

(2) Develop and implement an outreach plan to inform parents of children with disabilities and youth with disabilities in the identified community of how they can benefit from the services provided by the CPRC;

(3) Provide services that increase parents' capacity to help their children with disabilities improve their early learning, school-aged, and postsecondary outcomes. To meet this requirement, the applicant must include information as to how the services will—

(i) Increase parents' knowledge of—

(A) The nature of their children's disabilities, including their children's strengths and academic, behavioral, and developmental challenges;

(B) The importance of having high expectations for their children and how to help them meet those expectations;

(C) The local, State, and Federal resources available to assist them and their children, and local resources that strengthen their connection to their community;

(D) IDEA, Federal IDEA regulations, and State implementation of IDEA, including parents' role on Individualized Family Service Plan (IFSP) and Individualized Education Program (IEP) Teams and how to effectively participate on IFSP and IEP Teams;

(E) Other relevant educational and health care legislation, including the Elementary and Secondary Education Act of 1965, as amended (ESEA); section 504 of the Rehabilitation Act of 1973, as amended (section 504); and the Americans with Disabilities Act of 1990 (ADA);

(F) Transition services at all levels, including: Part C early intervention to Part B preschool, preschool to elementary school, elementary school to secondary school, and secondary school to postsecondary education and workforce options;

(G) How their children can have access to the general education curriculum, including access to college- and career-ready academic standards and assessments; inclusive early learning programs; inclusive general education classrooms and settings; vocational education; extracurricular and enrichment opportunities available to all children; and other initiatives to make students college- and career-ready;

(H) Evidence-based early intervention and education practices that improve early learning, school-aged, and postsecondary outcomes;

(I) Local school reform efforts to improve student achievement and increase graduation rates; and

(J) The use of data to inform instruction and advance school reform efforts;

(ii) Increase parents' capacity to—

(A) Effectively support their children with disabilities and participate in their children's education;

(B) Communicate effectively and work collaboratively in partnership with early intervention service providers, school-based personnel, related services personnel, and administrators;

(C) Resolve disputes effectively; and

(D) Participate in school reform activities to improve outcomes for all children;

(4) Provide services that increase youth with disabilities' capacity to be effective self-advocates. To meet this requirement, the applicant must include information as to how the services will—

(i) Increase the knowledge of youth with disabilities about—

(A) The nature of their disabilities, including their strengths, and their academic, behavioral, and developmental challenges;

(B) The importance of having high expectations for themselves and how to meet those expectations;

(C) The resources available to support their success in secondary and postsecondary education and employment and full participation in their communities;

(D) IDEA, section 504, ADA, and other legislation and policies that affect people with disabilities;

(E) Their rights and responsibilities while receiving services under IDEA and after transitioning to post-school programs, services, and employment;

(F) How they can participate on IEP Teams; and

(G) Supported decisionmaking necessary to transition to adult life; and

(ii) Increase the capacity of youth with disabilities to advocate for themselves, including communicating effectively and working in partnership with providers;

(5) Use various methods to deliver services that are appropriate in the context of the identified community;

(6) Use best practices to provide training and information to adult learners and youth in the identified community;

(7) Establish cooperative partnerships with any Parent Training and Information Center and any other CPRCs funded in the State under sections 671 and 672 of IDEA, respectively; and

(8) Network with local and State organizations and agencies, such as the Part C State Interagency Coordinating Council, the Part B State Advisory Panel, and protection and advocacy agencies that serve parents and families of children with disabilities, to better support the families and children with disabilities in the identified community to effectively and efficiently access IDEA services.

(c) Demonstrate, in the narrative section of the application, under ''Quality of the Evaluation Plan,'' how—

(1) The applicant will evaluate how well the goals or objectives of the proposed project, as described in its logic model, have been met, including a description of how the applicant will measure the outcomes proposed in the logic model (see paragraph (f)(1) of this priority). The description must include—

(i) Proposed evaluation methodologies appropriate to the scope of the project and the identified community, including proposed instruments, data collection methods, and analyses; and

(ii) Proposed criteria for determining if the project has reached and served families and youth in the identified community; and

(2) The proposed project will use the evaluation results to examine its implementation and its progress toward achieving intended outcomes.

(d) Demonstrate, in the narrative section of the application under ''Adequacy of Project Resources,'' how—

(1) The proposed personnel, consultants, and contractors have the qualifications and experience to carry out the proposed activities and achieve the intended outcomes identified in the project logic model (see paragraph (f)(1) of this priority);

(2) The applicant will encourage applications for employment from persons who are members of groups that have historically been underrepresented based on race, color, national origin,

linguistic diversity, gender, age, or disability, as appropriate; and

(3) The applicant and key partners have adequate resources to carry out the proposed activities.

(e) Demonstrate, in the narrative section of the application under ''Quality of the Management Plan,'' how—

(1) The proposed management plan will ensure that the intended outcomes identified in the project logic model (see paragraph (f)(1) of this priority) will be achieved on time and within budget;

(2) The time of key personnel, consultants, and contractors will be sufficiently allocated to the project;

(3) The proposed management plan will ensure that the services provided are of high quality;

(4) The board of directors will be used to provide appropriate oversight to the project;

(5) The proposed project benefits from a diversity of perspectives, including those of parents, providers, and administrators in the identified community;

(6) The proposed project will ensure that the Annual Performance Reports submitted to the Department will—

(i) Be accurate and timely;

(ii) Include information on the projects' outputs and outcomes; and

(iii) Include, at a minimum, the number and demographics of parents and youth to whom the CPRC provided information and training, and the levels of service provided to them; and

(7) The project management and staff will—

(i) Make use of the technical assistance (TA) and products provided by the Center on Parent Information and Resources, Regional Parent Technical Assistance Centers (PTACs), Native American PTAC, Military PTAC, and other TA centers funded by the Office of Special Education Programs (OSEP), as appropriate, including the PROMISE TA Center, in order to serve parents of children with disabilities and youth with disabilities as effectively as possible;

(ii) Participate in developing individualized TA plans with the Regional PTAC as appropriate; and

(iii) Facilitate one site visit from the Regional PTAC during the grant cycle.

(f) In the narrative or appendices as directed, the applicant must—

(1) Include, in Appendix A, a logic model that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project. A logic model communicates how a project will achieve its intended outcomes and provides a framework for both the formative and summative evaluations of the project;

NOTE: The following Web sites provide more information on logic models: *www.osepideasthatwork.org/logicModel* and *www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework.*

(2) Include, in Appendix A, person-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative; and

(3) Include, in the budget, attendance by the project director at one OSEP meeting in Washington DC annually, to be determined by OSEP;

NOTE: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director and other authorized representatives.

Definitions: For the purposes of this priority:

Evidence-based means supported by strong theory.

Strong theory means a rationale for the proposed process, product, strategy, or practice that includes a logic model.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority and requirements in this notice.

Program Authority: 20 U.S.C. 1472 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

NOTE: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

NOTE: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $27,411,000 for the Training and Information for Parents of Children with Disabilities program for FY 2017, of which we intend to use an estimated $700,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2018 from the list of unfunded applications from this competition.

Estimated Average Size of Awards: $100,000.

Maximum Award: We will reject any application that proposes a budget exceeding $100,000 for a single budget period of 12 months.

Estimated Number of Awards: 7.

NOTE: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

III. Eligibility Information

1. *Eligible Applicants:* Local parent organizations.

NOTE: Section 672(a)(2) of IDEA defines a ''local parent organization'' as a parent organization, as defined in section 671(a)(2), that—

(a) Has a board of directors the majority of whom are parents of children with disabilities ages birth through 26 from the community to be served; and

(b) Has as its mission serving families of children with disabilities who—

(i) Are ages birth through 26; and

(ii) Have the full range of disabilities described in section 602(3) of IDEA.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Eligible Subgrantees:* (a) Under 34 CFR 75.708(b) and (c) a grantee may award subgrants—to directly carry out project activities described in its application—to the following types of entities: State educational agencies; LEAs, including public charter schools that are considered LEAs under State law; IHEs; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian tribes or tribal organizations; and for-profit organizations suitable to carry out the activities proposed in the application.

(b) The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements*:

(a) Recipients of funding under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant for, and recipient of, funding under this program must involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet, from the Education Publications Center (ED Pubs), or from the program office.

To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this competition as follows: CFDA number 84.328C.

To obtain a copy from the program office, contact: Carmen Sanchez, U.S. Department of Education, 400 Maryland Avenue SW., room 5175, Potomac Center Plaza, Washington DC 20202–5076. Telephone: (202) 245–6595. If you use a TDD or TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit and double-spacing requirements do not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the page limit and double-spacing requirements do apply to all of Part III, the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

We will reject your application if you exceed the page limit in the application narrative section; or if you apply standards other than those specified in the application package.

3. *Submission Dates and Times:*

Applications Available: December 7, 2016.

Deadline for Transmittal of Applications: February 6, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: April 6, 2017.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

NOTE: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov*.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account,

we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Community Parent Resource Centers competition, CFDA number 84.328C, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Community Parent Resource Centers competition at *www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.328, not 84.328C).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov*. In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF. Additional, detailed information on how to attach files is in the application instructions.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.gov System: If you are

experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under *For Further Information Contact* in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

NOTE: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Carmen Sanchez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5175, Potomac Center Plaza, Washington, DC 20202–5076. FAX: (202) 245–7590.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.328C), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

NOTE: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.328C), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:*

In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as

peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Training and Information for Parents of Children with Disabilities program. The measures focus on the extent to which projects provide high-quality products and services, the relevance of project products and services to educational and early intervention policy and practice, and the use of products and services to improve educational and early intervention policy and practice. Projects funded under this competition are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Carmen Sanchez, U.S. Department of Education, 400 Maryland Avenue SW., Room 5175, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–6595.

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW.,

Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: December 2, 2016.

Sue Swenson,

Deputy Assistant Secretary for Special Education and Rehabilitative Services, delegated the authority to perform the functions and duties of the Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2016–29370 Filed 12–6–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0107]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; State Longitudinal Data System (SLDS) Survey 2017–2019

AGENCY: Department of Education (ED), National Center for Education Statistics (NCES).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 6, 2017.

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–2016–ICCD–0107. 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, 400 Maryland Avenue SW., LBJ, Room 2E–343, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: State Longitudinal Data System (SLDS) Survey 2017–2019.

OMB Control No.: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 112.

Abstract: As authorized by the Educational Technical Assistance Act of 2002, Title II, the Statewide Longitudinal Data Systems (SLDS) Grant Program has awarded competitive, cooperative agreement grants to states since 2005. Through grants and a growing range of services and resources, the program has helped propel the successful design, development, implementation, and expansion of K–12 and P–20W (early learning through the workforce) longitudinal data systems. These systems are intended to enhance the ability of States to efficiently and accurately manage, analyze, and use education data, including individual student records. The SLDSs should help states, districts, schools, educators, and other stakeholders to make data-informed decisions to improve student learning and outcomes; as well as to facilitate research to increase student achievement and close achievement gaps. The SLDS grants extend for three to five years for up to twenty million dollars per grantee, and grantees are obligated to submit annual reports and a final report on the development and implementation of their systems. All 50 states, five territories, and the District of Columbia are eligible to apply, and each state can apply multiple times to develop different aspects of their data system. Since November 2005, 97 grants have been awarded. In addition to the grants, the program offers many services and resources to assist education agencies with SLDS-related work. Best practices, lessons learned, and non-proprietary products/solutions developed by recipients of these grants and other states are disseminated to aid all state and local education agencies. This request is to formalize the annual SLDS Interim Progress Report (IPR) as the SLDS Survey, intended to provide insight on state and U.S. territory SLDS capacity for automated linking of K–12, teacher, postsecondary, workforce, career and technical education (CTE), adult education, and early childhood data. The SLDS Survey will help inform ongoing evaluation and targeted technical assistance efforts to enhance the quality of the SLDS Program's support to states. This submission is to conduct the annual SLDS Survey from 2017 through 2019.

Dated: December 1, 2016.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–29263 Filed 12–6–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974, as Amended; Computer Matching Program Between the U.S. Department of Education and the Department of Veterans Affairs

AGENCY: Department of Education.

ACTION: Notice.

SUMMARY: This document provides notice of the computer matching program between the U.S. Department of Education (ED) and the Department of Veterans Affairs (VA). The computer matching program will begin on the effective date specified in paragraph 5.

SUPPLEMENTARY INFORMATION: This notice is provided under the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101–508)(Privacy Act); the Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A–130, Appendix 1.

1. *Name of Participating Agencies.* ED and VA.

2. *Purpose of the Match.*The computer matching program will assist ED in its obligation to ensure that borrowers with disabilities who have loans under title IV of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070 *et seq.*), more efficiently and effectively apply for total and permanent disability discharge of their student loans.

3. *Authority for Conducting the Matching Program.* ED's legal authority to enter into this computer matching program is section 437 of the HEA (20 U.S.C. 1087(a)); the regulations promulgated pursuant to that 552a(a)(8)). VA's legal authority to enter into this computer matching program and to disclose information thereunder is the Privacy Act (5 U.S.C. 552a(a)(8) and (b)(3)).

4. *Categories of Records and Individuals Covered by the Match.* The records to be used in the match are described as follows:

VA will disclose to ED the name (first and last), date of birth, Social Security Number, and date of disability determination for individuals who are in receipt of VA disability compensation benefits with a VA disability compensation rating of 100 percent Permanent and Total.

ED will match the file received from VA with ED's records on individuals who owe a balance on one or more title IV, HEA loans or who have had a loan written off due to default, as contained in ED's system of records entitled ''National Student Loan Data System (NSLDS)'' (18–11–06), last published in the **Federal Register** in full on June 28, 2013 (78 FR 38963–38969) and last updated on April 2, 2014 (79 FR 18534–18536).

The ED data described in the preceding paragraph will be matched with the VA system of records identified as ''BIRLS—VA'' (38VA21), first published at 49 FR 38095 (August 26, 1975), routine use 21, as added by 66 FR 30049–30050 (June 4, 2001), which is the published system notice that added routine use 21 to this system of records notice.

5. *Effective Date of the Matching Program.* The computer matching program will become effective at the latest of the following dates: (1) The date of the last signatory to this Computer Matching Agreement; (2) 40 days after the signing of the transmittal letter sending the computer matching program report to Congress and OMB, unless OMB disapproves the matching program within the 40-day review period; (3) if OMB waives 10 or fewer days of the 40-day review period for compelling reasons, then 30 days plus whatever number of the 10 days that OMB did not waive after the signing of the transmittal letter sending the computer matching program report to Congress and OMB; or (4) 30 days after publication of this notice in the **Federal Register.** The matching program will continue for 18 months after the effective date and may be extended for an additional 12 months if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

6. *Address for Receipt of Public Comments or Inquiries.* Individuals wishing to comment on this matching program or obtain additional information about the program, including requesting a copy of the computer matching agreement between ED and VA, may contact Lisa Oldre, Program Operations Specialist, Federal Student Aid, U.S. Department of Education, 830 First Street NE., Washington, DC 20202–5320. Telephone: 202–377–3249. As a secondary contact, individuals may contact Pam Eliadis, Service Director, System Operations & Aid Delivery Management, Federal Student Aid, U.S. Department of Education, 830 First Street NE., Washington, DC 20202–5320. Telephone: (202) 377–3554.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (*e.g.,* braille, large print, audiotape, or compact disc) on request to either contact person listed in the previous paragraph.

Electronic Access to the Document: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of ED published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of ED published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by ED.

Authority: The Privacy Act of 1974, as amended (5 U.S.C. 552a).

Dated: December 2, 2016.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2016–29364 Filed 12–6–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and Arms Control, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a subsequent arrangement under the Agreement for Cooperation Between the United States of America and the Republic of Kazakhstan Concerning Peaceful Uses of Nuclear Energy and the Agreement for Cooperation Between the Government of the United States of America and the Government of Japan Concerning Peaceful Uses of Nuclear Energy.

DATES: This subsequent arrangement will take effect no sooner than December 22, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Richard S. Goorevich, Office of Nonproliferation and Arms Control, National Nuclear Security Administration, Department of Energy.

Telephone: 202–586–3806 or email: *Richard.Goorevich@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns the retransfer of 26,510,383 g of U.S.-origin enriched uranium oxide (UO2), containing 1,003,443 g of the isotope U–235 (less than five percent enrichment) which is recovered uranium from fuel fabrication scrap, from Ulba Metallurgical Plant in Ust-Kamengorsk, Kazakhstan, to Nuclear Fuel Industries, Ltd. in Minato-Ku, Tokyo, Japan. The material, which has already been retransferred to from Ulba to Nuclear Fuel Industries, Ltd., was to be fabricated into fuel pellets for electric utilities in Japan.

In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security of the United States of America.

Dated: November 28, 2016.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2016–29334 Filed 12–6–16; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2016–0695; FRL 9956–18–OLEM]

Hazardous Waste Electronic Manifest System (''e-Manifest'') Advisory Board; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be an inaugural three (3) day meeting of the Hazardous Waste Electronic Manifest System (''e-Manifest'') Advisory Board to consider and advise the Agency about the initial launch of the e-Manifest System (Meeting Theme: ''*System Launch: Day 1 e-Manifest*'').

DATES: The meeting will be held on January 10–12, 2017, from approximately 9:00 a.m. to 5:00 p.m. EST.

Comments. The Agency encourages written comments be submitted on or before December 27, 2016, and requests for oral comments be submitted on or before January 3, 2017. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after January 3, 2017, should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Webcast. This meeting may be webcast. Please refer to the e-Manifest Web site at *https://www.epa.gov/hwgenerators/hazardous-waste-electronic-manifest-system-e-manifest* for information on how to access the webcast. Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES: *Meeting:* The meeting will be held at the Crystal City Marriot at Reagan National Airport located on 1999 Jefferson Davis Hwy, Arlington, VA 22202.

Comments. Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2016–0695 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Fred Jenkins, Designated Federal Officer (DFO), U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5303P), 1200 Pennsylvania Avenue NW., Washington, DC 20460, Phone: 703–308–7049; or by email: *jenkins.fred@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of particular interest to persons who are or may be subject to the Hazardous Waste Electronic Manifest Establishment (e-Manifest) Act. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this document. To ensure proper receipt of your public comments by EPA, it is imperative that you identify docket ID number EPA–HQ–OLEM–2016–0695.

1. *Written comments.* The Agency encourages written comments be submitted electronically via regulations.gov, using the instructions in the **ADDRESSES** *Comments* section on or before December 27, 2016, to provide the e-Manifest Advisory Board the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after December 27, 2016, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring fifteen (15) copies for distribution to the e-Manifest Advisory Board.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments to the e-Manifest Advisory Board to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before January 3, 2017, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting. To the extent that time permits, the Chair of the e-Manifest Advisory Board may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) that the individual represents, and any requirements for audiovisual equipment. Oral comments before the e-Manifest Advisory Board are limited to approximately 5 minutes

unless prior arrangements have been made. In addition, each speaker should bring fifteen (15) copies of his or her comments and presentation for distribution to the e-Manifest Advisory Board at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

C. Purpose of the e-Manifest Advisory Board

The Hazardous Waste Electronic Manifest System Advisory Board is established in accordance with the provisions of the Hazardous Waste Electronic Manifest Establishment Act, 42 U.S.C. 6939g, and the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2. The e-Manifest Advisory Board is in the public interest and supports the Environmental Protection Agency in performing its duties and responsibilities.

The e-Manifest Advisory Board will provide recommendations on matters related to the operational activities, functions, policies, and regulations of EPA under the e-Manifest Act, including:

- The effectiveness of the Manifest IT system and associated user fees and processes;
- Matters and policies related to the e-Manifest program;
- Regulations and guidance as required by the e-Manifest Act;
- Actions to encourage the use of the electronic (paperless) system;
- Changes to the user fees as described in e-Manifest Act Section 2 (c)(3)(B)(i); and
- Issues in the e-Manifest area, including those identified in EPA' s E-Enterprise strategy that intersect with the e-Manifest system, such as:
- Business to business communications;
- Performance standards for mobile devices; and
- EPA's Cross Media Electronic Reporting Rule (CROMERR) requirements.

The sole duty of the Advisory Board is to provide advice and recommendations to the EPA Administrator. As required by the e-Manifest Act, the e-Manifest Advisory Board will be composed of nine (9) members. One (1) member will be the EPA Administrator (or a designee), who will serve as Chairperson of the Advisory Board. The rest of the committee will be composed of:

- At least two (2) members who have expertise in information technology;
- At least three (3) members who have experience in using or represent users of the manifest system to track the transportation of hazardous waste under the e-Manifest Act;
- At least three (3) members who will be state representatives responsible for processing e-manifests.

All members of the e-Manifest Advisory Board, with the exception of the EPA Administrator, will be appointed as Special Government Employees or representatives.

D. Public Meeting

The EPA will convene the e-Manifest Advisory Board to hold its first Federal Advisory Committee meeting. The meeting theme will be entitled ''*System Launch: Day 1 e-Manifest*''. The purpose of the meeting is to address critical policy and system development issues that need resolution prior to launching the e-Manifest system. Specifically, the Advisory Board will provide recommendations to the EPA on setting and revising user fees for users of the e-Manifest system. The Advisory Board will also advise the EPA on system development matters, such as critical functionality needed on Day One of the implementation of e-Manifest, and mechanisms that may encourage early adoption of e-Manifest once the e-Manifest becomes available to the manifest user community.

E. e-Manifest Advisory Board Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to the Advisory Board, the Advisory Board roster (*i.e.,* members attending this meeting), and the meeting agenda will be available by approximately mid-December 2016. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available at *http://www.regulations.gov* and the e-Manifest Advisory Board Web site at: *https://www.epa.gov/hwgenerators/hazardous-waste-electronic-manifest-system-e-manifest.* The e-Manifest Advisory Board will prepare meeting minutes summarizing its recommendations to the Agency approximately ninety (90) days after the meeting. The meeting minutes will be posted on the e-Manifest Advisory Board Web site or may be obtained from the docket at *http://www.regulations.gov.*

Dated: November 30, 2016.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery, Office of Land and Emergency Management.

[FR Doc. 2016–29340 Filed 12–6–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011223–055.

Title: Transpacific Stabilization Agreement.

Parties: American President Lines, Ltd. and APL Co. PTE Ltd.; (operating as a single carrier); Maersk Line A/S; CMA CGM, S.A.; COSCO Container Lines Company Ltd; Evergreen Line Joint Service Agreement; Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Mediterranean Shipping Company; Orient Overseas Container Line Limited; Yangming Marine Transport Corp.; and Zim Integrated Shipping Services, Ltd.

Filing Party: Robert Magovern, Esq.; Cozen O'Connor; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The amendment revised Appendix A of the TSA Agreement to remove Hanjin Shipping Co., Ltd., as a party to the Agreement.

Agreement No.: 012444.

Title: ZIM/MOL Equipment Repositioning Agreement.

Parties: Mitsui O.S.K. Lines, Ltd. and Zim Integrated Shipping Services Co., Ltd.

Filing Party: Joshua P. Stein; Cozen O'Connor; 1200 Nineteenth Street NW., Washington DC, 20036.

Synopsis: The Agreement authorizes ZIM and MOL to charter slots on each other's vessels for the carriage of empty containers on an ad hoc basis in the trade between ports on the East, Gulf and West Coast of the United States and ports in Europe, the Mediterranean, Canada, South America, and Asia.

Agreement No.: 012445.

Title: Port of New York/New Jersey Equipment Optimization Discussion Agreement.

Parties: Ocean Carrier Equipment Management Association Agreement (OCEMA) and the Port Authority of New York and New Jersey (Port Authority).

Filing Party: Jeffrey F. Lawrence and Donald J. Kassilke; Cozen O'Connor; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The Agreement would authorize the Parties to collect and exchange information, discuss, and reach agreement upon matters relating to cargo throughput, safety, intermodal equipment supply and efficiencies, congestion relief, port and terminal infrastructure, financing of improvements, and clean air or other environmental initiatives affecting operations in and around the Port of New York and New Jersey.

By Order of the Federal Maritime Commission.

Dated: December 2, 2016.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–29365 Filed 12–6–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: 10:00 a.m., Tuesday, December 13, 2016.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Closed.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in closed session: *Daniel B. Lowe and Matthew Varady* v. *Veris Gold USA, Inc., et al.* (Issues include whether the Administrative Law Judge erred in dismissing two discrimination cases where the original operator was the subject of bankruptcy proceedings.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Dated: December 5, 2016.

Emogene Johnson,

Administrative Assistant.

[FR Doc. 2016–29450 Filed 12–5–16; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board or Federal Reserve) is adopting a proposal to revise, with extension, the mandatory Savings Association Holding Company Report. The revision to this mandatory information is effective December 31, 2016.

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW.,Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, with revision, of the following report:

Report title: Savings Association Holding Company Report.

OMB control number: 7100–0334.

Agency form number: FR H–(b)11.

Frequency: Quarterly.

Reporters: Savings and Loan Holding Companies.

Effective Date: December 31, 2016.

Estimated number of respondents: 15.

Estimated average hours per response: 2 hours.

Estimated annual burden hours: 120 hours.

General Description of Report: The FR H–(b)11 is authorized by Section 10 of the Home Owners' Loan Act, which requires savings and loan holding companies (SLHCs) to file ''such reports as may be required by the Board'' and provides that such reports ''shall contain such information concerning the operations of such SLHC and its subsidiaries as the Board may require'' (12 U.S.C. 1467a(b)(2)(A)). The information collection is available to the public upon request through the appropriate Federal Reserve Bank. The Federal Reserve Board uses the FR H–(b)11 data to analyze the overall financial condition of SLHCs to ensure safe and sound operations.

Current actions: On July 22, 2016, the Federal Reserve published an initial notice in the **Federal Register** [1] requesting public comment for 60 days on the extension, with revision, of the FR H–(b)11. The Board proposed to eliminate the requirement that a publicly-traded SLHC submit a copy of its filings with the SEC. The comment period for this notice expired on September 20, 2016. The Board did not receive any comments. The revision will be implemented as proposed.

Legal authorization and confidentiality: The FR H–(b)11 is mandatory and its collection is authorized by Section 10 of the Home Owners' Loan Act, which requires SLHCs to file ''such reports as may be required by the Board'' and provides that such reports ''shall contain such information concerning the operations of such SLHC and its subsidiaries as the Board may require'' (12 U.S.C. 1467a(b)(2)(A)).

The FR H–(b)11 covers 6 different items. Item 1 consists of SEC filings made by the SLHC that are not publicly traded companies and item 2 consists of reports provided by nationally recognized statistical rating organizations and securities analysts on any company in the SLHC's consolidated organization. The Board's Legal Division has determined that neither of these items should raise any issue of confidentiality.

Item 3 consists of supplemental information for any questions on the FR 2320 to which the SLHC answered ''yes.'' The Board's Legal Division has determined that supplemental information in response to a ''yes'' answer for the FR 2320's questions 24, 25, and 26 may be protected from disclosure under exemption 4 of the Freedom of Information Act (FOIA), which covers ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential'' (5 U.S.C. 522(b)(4)). These questions concern any

[1] See 81 FR 47801.

new or changed pledges of capital stock of any subsidiary savings association that secures short-term or long-term debt or other borrowings of the SLHC; changes to any class of securities of the SLHC or any of its subsidiaries that would negatively impact investors; and any default of the SLHC or any of its subsidiaries during the quarter. Disclosure of this type of information is likely to cause substantial competitive harm to the SLHC providing the information and thus this information may be protected from disclosure under FOIA exemption 4 (5 U.S.C. 522(b)(4)).

With regard to the supplemental information for other FR 2320 questions that would be provided in item 3 of the FR H–(b)11, as well as item 4 (Other Materially Important Events), item 5 (Financial Statements) and item 6 (Exhibits—essentially copies not previously filed of its charter or bylaws), the respondent may request confidential treatment of such information under one or more of the exemptions in the FOIA. The most likely case for confidential treatment will be exemption 4 (5 U.S.C. 522(b)(4)). However, all such requests for confidential treatment would need to be reviewed on a case-by-case basis and in response to a specific request for disclosure.

Board of Governors of the Federal Reserve System, December 2, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–29330 Filed 12–6–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board or Federal Reserve) is adopting a proposal to extend for three years all of the Financial Reports of Foreign Banking Organizations: The Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations (FR Y–7N), the Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations (FR Y–7NS), and the mandatory Capital and Asset Report for Foreign Banking Organizations (FR Y–7Q); with revisions to the FR Y–7Q, effective December 31, 2016, except for three new FR Y–7Q items, which are effective March 31, 2018.

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, with revision, of the following information collection:

Report titles: Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, and Capital and Asset Report for Foreign Banking Organizations.

Agency form numbers: FR Y–7N, FR Y–7NS, and FR Y–7Q.

OMB control number: 7100–0125.

Frequency: Quarterly and annually.

Effective Dates: Reporting period ending on December 31, 2016, except for three new FR Y–7Q items, which are effective March 31, 2018.

Respondent type: Foreign banking organizations (FBOs).

Estimated annual reporting hours: FR Y–7N (quarterly): 1,170 hours; FR Y–7N (annual): 218 hours; FR Y–7NS: 40 hours; FR Y–7Q (quarterly): 1,632 hours; FR Y–7Q (annual): 48 hours.

Estimated average hours per response: FR Y–7N (quarterly): 6.8 hours; FR Y–7N (annual): 6.8 hours; FR Y–7NS: 1 hour; FR Y–7Q (quarterly): 3 hours; FR Y–7Q (annual): 1.5 hours.

Number of respondents: FR Y–7N (quarterly): 43; FR Y–7N (annual): 32; FR Y–7NS: 40; FR Y–7Q (quarterly): 136; FR Y–7Q (annual): 32.

Legal authorization and confidentiality: This information collection is mandatory pursuant to section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)) and sections 8(c) and 13 of the International Banking Act (12 U.S.C. 3106(c) and 3108)). Section 165 of the Dodd-Frank Act (12 U.S.C. 5365) directs the Federal Reserve to establish enhanced prudential standards for certain companies, including certain FBOs. Information disclosed in these reports is collected as part of the Board's supervisory process and may be accorded confidential treatment under Exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)), but information that is required to be disclosed publicly is generally not considered confidential. However, individual respondents may request that certain data be protected pursuant to Exemptions 4 and 6 (5 U.S.C. 552(b)(4) & (6)) of FOIA, where such data relates to trade secrets and financial information, or to personal information, respectively. The applicability of these exemptions would have to be determined on a case-by-case basis.

Abstract: The FR Y–7N and FR Y–7NS collect financial information for non-functionally regulated U.S. nonbank subsidiaries held by FBOs other than through a U.S. bank holding company (BHC), FHC, or U.S. bank. FBOs file the FR Y–7N quarterly or annually or the FR Y–7NS annually predominantly based on asset size thresholds. The FR Y–7Q collects consolidated regulatory capital information from all FBOs either quarterly or annually. The FR Y–7Q is filed quarterly by FBOs that have effectively elected to become U.S. financial holding companies (FHCs) and by FBOs that have total consolidated assets of $50 billion or more, regardless of FHC status. All other FBOs file the FR Y–7Q annually.

Current Actions: On April 4, 2016, the Federal Reserve published a notice in the **Federal Register** requesting public comment for 60 days on the extension, with revision, of the FR Y–7N, FR Y–7NS, and FR Y–7Q.[1] The comment period for this notice expired on June 3, 2016. In general, the commenters supported the proposed changes, but requested clarification on the home country capital adequacy certification requirement and the confidentiality and disclosure requirements for the proposed home country capital information. The Federal Reserve previously proposed to collect fourteen

[1] 81 FR 19179 (April 4, 2016).

new data items to monitor compliance with enhanced prudential standards for FBOs adopted pursuant to Subparts N and O of Regulation YY. As discussed below, as a result of commenters' general concerns regarding confidentiality, such as with respect to non-public supervisory capital buffers, the Federal Reserve now proposes to collect twelve new data items.

On February 18, 2014, the Board approved a final rule, pursuant to section 165 of the Dodd-Frank Act, that requires an FBO with total consolidated assets of $50 billion or more to certify to the Board that it meets capital adequacy standards on a consolidated basis, as established by its home-country supervisor, that are consistent with the regulatory capital framework published by the Basel Committee on Banking Supervision.[2] This requirement was intended to help ensure that the consolidated capital base supporting the activities of U.S. branches and agencies remains strong, and to lessen the degree to which weaknesses at the consolidated foreign parent could undermine the financial strength of its U.S. operations. The following new data items would be used to determine whether an FBO with total consolidated assets of $50 billion or more meets capital adequacy standards at the consolidated level that are consistent with the Basel Capital Framework.

Part 1B (New Section for FBOs >$50 Billion in Total Assets)

The proposal would require an FBOs with total consolidated assets of $50 billion or more to complete a new section, Part 1B, effective December 31, 2016 (with three of the proposed items effective March 31, 2018). Proposed Part 1B would contain 12 items related to home country regulatory capital ratios that would be reported on a quarterly basis.[3] The value of each of these items would be calculated on a consolidated basis according to the methodologies established by the FBO's home-country supervisor that are consistent with the Basel Capital Framework, as defined in Regulation YY.[4] If the home-country supervisor has not established capital adequacy standards consistent with the Basel Capital Framework, the value of these items would be calculated on a pro-forma basis as if the FBO were subject to such standards. The proposed line items that would be effective December 31, 2016, include:

(1) Common equity tier 1 capital,
(2) Additional tier 1 capital,
(3) Tier 1 capital (sum of items 1 and 2),
(4) Tier 2 capital,
(5) Total risk-based capital (sum of items 3 and 4),
(6) Capital conservation buffer,
(7) Countercyclical capital buffer,
(8) GSIB buffer,
(9) Compliance with restrictions on capital distributions and discretionary bonus payments associated with a capital buffer.

The proposed line items that would be effective March 31, 2018, include:

(10) Home country capital measure used in the numerator of the leverage ratio as set forth in the Basel Capital Framework,
(11) Home country exposure measure used in the denominator of the leverage ratio as set forth in the Basel Capital Framework,
(12) Minimum home country leverage ratio (if different from the leverage ratio in the Basel Capital Framework, as applicable).

Part 1A (Renaming Existing Part 1 Section Applicable to All FBOs)

As noted above, Part 1A of the current FR Y–7Q form, which applies to all FBOs, collects tier 1 capital, total risk-based capital, risk-weighted assets, total consolidated assets and total combined assets of U.S. operations, net of intercompany balances and transactions between U.S. domiciled affiliates, branches, and agencies, and total U.S. non-branch assets. While the Federal Reserve does not propose to change existing items reported in Part 1A of the FR Y–7Q, the proposal would modify the instructions to clarify that an FBO would be required to report Tier 1 capital and Total risk-based capital only on Part 1B, if the FBO's home country methodologies are consistent with the Basel Capital Framework.

The instructions would also clarify the reporting frequency of Part 1, in light of the new proposed section. Specifically, FBOs with total consolidated assets of less than $50 billion and that are not FHCs would only file Part 1A on an annual basis. FBOs who have elected to become FHCs and do not have $50 billion or more in total consolidated assets will file Part 1A on a quarterly basis. FBOs with total consolidated assets of $50 billion or more would complete both Part 1A *and* Part 1B on a quarterly basis.

The Federal Reserve recommends no changes to the reporting frequency of the FR Y–7N/NS and FR Y–7Q. The current reporting frequencies provide adequate timely data to meet the analytical and supervisory needs of the Federal Reserve.

Detailed Discussion of Public Comments

1. Certification Requirement

A commenter requested guidance on whether an FBO would be deemed to satisfy the requirement to report and certify compliance with its home country capital adequacy requirements through its FR Y–7Q report. In addition, the commenter asked the Board to confirm the as of date and frequency of the certification.

Regulation YY requires an FBO to report compliance with capital adequacy measures that are consistent with the Basel Capital Framework (as defined in 12 CFR 252.143(a) and § 252.154(a)) concurrently with filing the FR Y–7Q; however it does not specify the frequency or the as of date for an FBO's certification of compliance with its home country capital requirements. The Board confirms that an FBO's completion of the FR Y–7Q on a quarterly basis would satisfy both the requirement to report and the requirement to certify to the Board its compliance with capital adequacy measures that are consistent with the Basel Capital Framework. If an FBO is unable to report that it is in compliance with such capital adequacy measures, the Board may impose requirements, conditions, and restrictions relating to the U.S. operations of the FBO.[5]

2. Confidentiality Determinations

Commenters raised concerns regarding the potential confidentiality of two items required to be reported in the proposal that may be considered non-public supervisory capital buffers by an FBO's home country supervisor: the Pillar II buffer and any ''other'' applicable capital buffer. In response to these concerns, the Board has reviewed the information it proposed to collect on the FR Y–7Q and has revised the proposal to eliminate these two items from the information collection and only collect 12 new data items, each of which are expected to be disclosed

[2] *See* 12 CFR part 252. Regulation YY provides that home country capital standards that are consistent with the Basel Capital Framework include all minimum risk-based capital ratios, any minimum leverage ratio, and all restrictions based on any applicable capital buffers set forth in ''Basel III: A global regulatory framework for more resilient banks and banking systems.'' Basel III was published in December 2010 and revised in June 2011. The text is available at *http://www.bis.org/publ/bcbs189.htm*.

[3] The Board had initially proposed to collect two additional line items: The Pillar II buffer and any ''other'' applicable capital buffer; however, in response to comments on the proposal, the Board no longer proposes to collect this information.

[4] *See* 12 CFR part 252.143 and 252.154.

[5] *See* 12 CFR part 252.143(c) and 252.154(c).

publicly under the Basel Capital Framework, to monitor compliance with enhanced prudential standards for FBOs in Regulation YY. These 12 new data items would include, among other items, information relating to the capital conservation buffer, countercyclical capital buffer, and global systemically important banking organization capital buffer.

A commenter also requested that the Board expand the confidential treatment for certain of the proposed new items. The proposal stated that the Board would determine confidentiality on the proposed items reported on the FR Y–7Q on a case-by-case basis. However, the proposal noted that some jurisdictions may treat the information collected as confidential on a blanket basis on the grounds that a more selective confidential treatment could signal an FBO's financial strength or weakness and could thereby cause substantial competitive harm. Therefore, the proposal invited comment on whether these items should qualify for confidential treatment in all cases, such that treating this information as confidential on a blanket basis would be appropriate.

In response to the proposal, a commenter suggested the following modifications to the Board's proposed ''case-by-case'' approach: (1) Where a home country supervisor treats an item included in Part 1B as confidential on a blanket basis, the Board likewise should extend blanket confidential treatment of that item to all FBOs supervised by the home country authority; and (2) where a home country supervisor treats an item included in Part 1B as confidential on a case-by-case basis, the Board should automatically treat this item as confidential for any FBO whose home country supervisor has extended such treatment.

As discussed above, in response to commenters' general concerns regarding confidentiality, the Board has revised the FR Y–7Q to collect only information that is expected to be disclosed under the Basel Capital Framework, and therefore will be public and not considered confidential. The Board further notes that information disclosed in these reports would be collected as part of the Board's supervisory process and may be accorded confidential treatment under Exemption 8 of FOIA. However, individual respondents may request that certain data be protected pursuant to Exemptions 4 and 6 of FOIA, where such data relates to trade secrets and financial information, or to personal information, respectively. The applicability of these exemptions will be determined on a case-by-case basis.

In addition, the proposed modification to the ''case-by-case'' approach set forth by one commenter would require the Federal Reserve to determine confidentiality for all FBOs supervised by a particular home-country authority on a country-by-country basis. An FBO seeking confidential treatment for any information reported on the FR Y–7Q must file a request pursuant to Exemption 4 of FOIA and state in reasonable detail the facts supporting the request and the legal justification for the request. Because the FBO is best suited to describe its home country supervisor's confidential treatment of information, the Federal Reserve relies on information provided by the FBO in making its determination of whether the release of that information would cause the FBO substantial competitive harm. In addition, the Federal Reserve may need additional information to support such a determination, and the home country supervisor's treatment of the information alone may not meet the standard for confidential treatment in Exemption 4 of FOIA in all cases. Accordingly, as proposed, the Federal Reserve would grant an FBO's request for confidential status for information reported on the FR Y–7Q, pursuant to Exemption 4 of FOIA, only on a case-by-case basis.

3. Prohibited Items

A commenter also requested that the Board confirm that an FBO would not be required to report any item where applicable home country law prohibits the FBO from disclosing such item to any person, except an appropriate home country supervisor, regardless of whether the other person would agree to keep such information strictly confidential.

The Board is authorized by law to collect information from an FBO regarding its financial condition and, in submitting to the Board's jurisdiction, an FBO is required to provide the Board with adequate assurances that information will be made available to the Board on the operations or activities of the FBO and any of its affiliates that the Board deems necessary to determine and enforce compliance with applicable federal banking statutes, including information on its consolidated regulatory capital information. Therefore, an FBO is required to provide all of the information requested on the FR Y–7Q report. However, there could be infrequent instances that may raise questions about an FBO's ability to report a particular item on the FR Y–7Q if home country law prohibits an FBO from reporting that information to the Board, and, in those limited circumstances, the Board may consider an FBO's request not to report that information on the FR Y–7Q, on a case-by-case basis.

Board of Governors of the Federal Reserve System, December 2, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–29329 Filed 12–6–16; 8:45 am]

BILLING CODE 6210–01–P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No. 112072016–1111–08]

Supplemental Notice Extending the Application Deadline for the Funded Priorities List

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Notice.

SUMMARY: Through this **Federal Register** notice (FRN), the Gulf Coast Ecosystem Restoration Council (Council) announces it is extending the deadline for Council members to submit applications to implement projects and programs approved on the 12/09/2015 Funded Priorities List (FPL) Addendum to the Initial Comprehensive Plan. Applications do not have to be submitted by December 31, 2016 and instead will be accepted on a rolling basis.

SUPPLEMENTARY INFORMATION: On December 31, 2015, the Council published an FRN (80 FR 81819) inviting Council members to apply for funding under the Council-Selected Restoration Component of the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 (RESTORE Act) (33 U.S.C. 1321(t)(2)) to implement projects and programs approved on the 12/09/2015 FPL Addendum to the Initial Comprehensive Plan. The December 31, 2015 FRN specified that applications were due by December 31, 2016. Through this notice, the Council announces that the deadline for applications is no longer December 31, 2016 and that applications will now be accepted on a rolling basis and are still to be submitted through the Restoration Assistance and Awards Management System (RAAMS). This notice does not change any other

portion of the December 31, 2015 FRN inviting applications.

Will D. Spoon,

Program Analyst, Gulf Coast Ecosystem Restoration Council.

[FR Doc. 2016–29369 Filed 12–6–16; 8:45 am]

BILLING CODE 6560–58–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17CP; Docket No. CDC–2016–0116]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed information collection project entitled ''Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika''.

DATES: Written comments must be received on or before February 6, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0116 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov.*

*Please note: All public comments should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Formative Assessment Regarding Contraception Use in the U.S. Virgin Islands (USVI) in the Context of Zika—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As of October 11, 2016, the U.S. Virgin Islands (USVI) Department of Health reported 1,320 Zika cases, in which 524 have been confirmed Zika cases.

Ongoing Zika virus transmission in the USVI intensifies the urgent public health need to increase contraceptive access for women who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes. Among the approximately 12,000 women at risk of unintended pregnancy (women of reproductive age, 18–44 years, who are sexually active and fertile, and not currently desiring a pregnancy) in the USVI, nearly half are not using highly or moderately effective contraception (long acting reversible methods [LARCs], including intrauterine devices [IUDs] and implants, or hormonal methods).

In response to the continued impact of the Zika virus in the USVI, CDC is proposing to develop a comprehensive communication strategy to raise awareness that pregnancy prevention in women who choose to delay or avoid pregnancy is a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes, as well as inform women about available contraceptive methods and services. To ensure the cultural appropriateness and relevance of this approach, CDC plans to conduct a formative assessment with women and men between the ages of 18 and 44 years in the USVI.

The goal of this information collection request is to qualitatively assess current knowledge, attitudes, and beliefs regarding contraception use, in general, and related to Zika virus exposure, in particular, in the USVI. We will explore perceived barriers to accessing contraception and effective ways to provide messages about the contraceptive methods and services available. Additionally, we will seek information on acceptable messaging strategies, including message content and related imagery, effective channels for message dissemination, and appropriate spokespersons and partners.

The intended use of the resulting data is for CDC to develop timely, relevant, clear, and engaging materials for the USVI regarding pregnancy prevention during the Zika outbreak.

CDC will use focus groups to collect the data. This methodology provides flexible in-depth exploration of the participants' perceptions and experience and yield descriptions in the participants' own words. Furthermore, the facilitator will have flexibility to pursue relevant and important issues as they arise during the discussion.

There is no cost to participants other than their time. The total estimated annualized burden hours are 144.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Women of reproductive age	Semi-structured qualitative focus group interview—females.	60	1	2	120
Men of reproductive age	Semi-structured qualitative focus group interview—males.	12	1	2	24
Total					144

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–29310 Filed 12–6–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award of Five Single-Source Low-Cost Extension Supplement Grants Within the Office of Refugee Resettlement's Unaccompanied Children's Program

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of award of five single-source low-cost extension supplement grants under the Unaccompanied Children's (UC) Program.

SUMMARY: ACF, ORR, announces the award of five single-source low-cost extension supplement grants for a total of $19,604,765 under the UC Program.

DATES: Low-cost extension supplement grants will support activities from October 1, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Director, Division of Children's Services, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: *DCSProgram@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following supplement grants will support the immediate need for additional capacity of shelter services to accommodate the increasing number of UC referred by the Department of Homeland Security (DHS) into ORR care. The increase in the UC population makes it necessary to expand the services to expedite the release of UC to designated sponsors. To prepare for an increase in referrals for shelter services, ORR will solicit proposals from one grantee to accommodate the referrals from DHS.

Grant No.	Grantee	Shelter current funding ending 9/30/16	Low-cost extension 10/1/16–12/31/16
Texas	International Educational Services, Inc.	$27,082,262	$6,926,653
Texas	International Educational Services, Inc.	15,451,597	6,701,163
Texas	International Educational Services, Inc.	6,180,591	1,582,169
Texas	International Educational Services, Inc.	8,269,202	2,057,311
Texas	International Educational Services, Inc.	9,148,344	2,337,469
Total		66,131,996	19,604,765

ORR is continuously monitoring its capacity to provide post-release services to UC in HHS custody.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing post-release services program through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility of safe and timely release of UC referred to its care by DHS. It also lets the U.S. Border Patrol continue its vital national security mission to prevent illegal migration and trafficking and protect the borders of the United States.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of UC from the Commissioner of the former Immigration and Naturalization Service to the Director of ORR in HHS.

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C. D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Christopher Beach,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration, Administration for Children and Families.

[FR Doc. 2016–29326 Filed 12–6–16; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3274]

Posting Adverse Event Report Data Associated With Conventional Foods, Dietary Supplements, and Cosmetics on the Internet; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of data extracted from adverse event reports from January 2004 to the present involving food (including food additives, color additives, and dietary supplements) and cosmetics regulated by our Center for Food Safety and Applied Nutrition (CFSAN). The data files are being made publicly available on FDA's Web site to improve transparency about adverse event reports involving CFSAN-regulated products and increase awareness about reporting these adverse events to FDA.

FOR FURTHER INFORMATION CONTACT: Lyle Canida, Center for Food Safety and Applied Nutrition (HFS–014), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1817.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of data extracted from the CFSAN Adverse Event Reporting System (CAERS) from adverse event reports involving food (including food additives, color additives, and dietary supplements) and cosmetics regulated by CFSAN that were submitted to FDA from January 2004 to the present. We will make these data files available on a quarterly basis on the FDA Web site at *http://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm.* Each posting will consist of adverse event report information entered in CAERS for the previous 3 months with a roughly one month delay. The data files are provided in ASCII format and include information on the following topics (if provided):

- Demographic (*e.g.,* age, gender) and administrative information regarding the adverse event;
- Date of event;
- Product role (suspect or concomitant);
- Reported brand/product name;
- Industry code/name;
- Reported symptom(s); and
- Outcome information.

What is CAERS?

The CAERS database collects reports submitted by consumers, health professionals, industry, and others about adverse health events and product complaints related to CFSAN-regulated products. It includes voluntary reports involving conventional foods, including food additives and color additives, and cosmetics, and both mandatory and voluntary reports with respect to adverse events involving dietary supplements. Reports are mandatory for dietary supplements used in the United States in the case of a serious adverse event that has resulted in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent one of those outcomes (*see* 21 U.S.C. 379aa–1). In such cases, dietary supplement manufacturers, packers, and distributors must notify FDA if they receive reports about serious adverse events associated with the use of the dietary supplement.

The goal of CAERS is to improve consumer protection by providing FDA with information from which we may be able to quickly identify situations in which the data provide a signal that a particular product may be harmful and should be investigated further.

However, we note that adverse event reports about a particular product and the total number of adverse event reports for a product in the CAERS database only reflect information reported and do not represent any conclusion by FDA about whether the product actually caused the adverse event(s). Because we constantly update CAERS with new information, the number of reports for a given product and the content of individual reports may change over time. Furthermore, even with respect to dietary supplements, for which reporting of serious adverse events is mandatory, adverse events associated with any product may be underreported. On the other hand, in some instances there may be duplicate reports in CAERS for the same adverse event because multiple people (such as an injured consumer and a health care provider who treated him or her) may have submitted reports. Questions and answers (Q&As) accompanying the data at our Web site explain the data limitations, as well as the reasons why we need complete reporting.

Why is CFSAN posting these data on the FDA Web site?

- We are making this information available for the purpose of improving transparency by providing the public, including researchers and health care professionals, with online access to information from adverse event reports about CFSAN-regulated products. This information has previously been available only through the process of specific requests under the Freedom of Information Act, 5 U.S.C. 552. In addition, we believe that posting these data may increase the number and completeness of the adverse event reports we receive. For the most part, FDA does not have pre-market authority over foods and cosmetics. As a result, identifying through post-market surveillance possible risks associated with these products is critical.

Where and when will data be posted?

- We will post CAERS data on a quarterly basis on the FDA Web site at *http://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm.* Each posting will include adverse event reports entered in CAERS for the previous 3 month period, with a roughly one month delay. So for example, if we post data files on the CAERS Web page in February, the information would consist of adverse event reports entered (or revised) in CAERS during the previous October thru December time period. Data files from the January thru March time period would be posted in the following May, and so on.

Dated: December 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29277 Filed 12–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA 2016–E–0630 and FDA–2016–E–1102]

Determination of Regulatory Review Period for Purposes of Patent Extension; GARDASIL 9

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GARDASIL 9 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 6, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 5, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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 Nos. FDA 2016–E–0630 and FDA–2016–E–1102 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; GARDASIL 9.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product GARDASIL 9

(Human papillomavirus 9-valent Vaccine, Recombinant). GARDASIL 9 is indicated in girls and women 9 through 26 years of age for the prevention of the following diseases:

- Cervical, vulvar, vaginal, and anal cancer caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58.
- Genital warts caused by HPV types 6 and 11.

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma in situ.
- CIN grade 1.
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3.
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 1.
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

Gardasil 9 is also indicated in boys and men 9 through 26 years for the prevention of the following diseases;

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58.
- Genital warts caused by HPV types 6 and 11.

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- AIN grades 1, 2, and 3.

Subsequent to this approval, the USPTO received patent term restoration applications for GARDASIL 9 (U.S. Patent Nos. 7,476,389 and 7,482,015) from Merck Sharp & Dohme Corp. for CSL Limited and The University of Queensland; the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 26, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of GARDASIL 9 represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for GARDASIL 9 is 2,662 days. Of this time, 2,296 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* August 29, 2007. The applicant claims September 2, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 29, 2007, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: December 10, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for GARDASIL 9 (BLA 125508/0) was initially submitted on December 10, 2013.

3. *The date the application was approved:* December 10, 2014. FDA has verified the applicant's claim that BLA 125508/0 was approved on December 10, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,062 days or 1,254 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see DATES). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: *December 1, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29303 Filed 12–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0937–0191–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0937–0191, scheduled to expire on December 31, 2016. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before January 6, 2017.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0937–0191–30D for reference.

Information Collection Request Title: Application packets for Real Property for Public Health Purposes.

OMB No.: 0937–0191.

Abstract: The Office of Assistant Secretary for Administration, Program Support Center, Federal Property Assistance Program is requesting OMB's approval on a previously approved information collection, 0937–0191. The Federal Property and Administrative Services Act of 1949 (P.L. 81–152), as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which (except for institutions which lease property to assist the homeless) have been held

exempt from taxation under Section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health and homeless assistance purposes. Transfers are made to transferees at little or no cost.

Need and Proposed Use of the Information: State and local governments and non-profit institutions use these applications to apply for excess/surplus, underutilized/unutilized and off-site government real property. These applications are used to determine if institutions/organizations are eligible to purchase, lease or use property under the provisions of the surplus real property program.

Likely Respondents: State, local, or tribal units of government or instrumentalities thereof; not-for-profit organizations

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Applications for surplus Federal real property	15	1	200	3,000
Total	15	1	200	3,000

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–29361 Filed 12–6–16; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before February 6, 2017.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–5683.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.funn@hhs.gov* or (202) 690–5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–New–60D for reference.

Information Collection Request Title: Domestic Violence Housing First Demonstration Evaluation

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services, in partnership with the Office for Victims of Crimes within the U.S. Department of Justice, is seeking approval by OMB for a new information collection request entitled, ''Domestic Violence Housing First (DVHF) Demonstration Evaluation.'' The Washington State Coalition Against Domestic Violence (WSCADV) is overseeing and coordinating an evaluation of the DVHF Demonstration project through a contract with ASPE. This quasi-experimental research study involves longitudinally examining the program effects of DVHF on domestic violence survivors' safety and housing stability. The findings will be of interest to the general public, to policy-makers, and to organizations working with domestic violence survivors.

Data collection will include in-depth, private interviews with 320 domestic violence survivors conducted by trained professional staff. At Time 1 study enrollment, they will be interviewed about their backgrounds, housing and safety obstacles, and services desired. There will be three follow-up interviews with them every six months after the Time 1 Interview (*i.e.,* 6, 12, and 18 months) to examine the match between needs and services, as well as their safety and housing stability. Study enrollment will take place over 15 months, so the annualized burden for the Time 1 and follow-up surveys is based on 12/15 (256) of the expected sample (320).

The primary service providers working with the domestic violence survivors will complete self-administered online questionnaires to provide more detailed program implementation data. Service providers will complete a survey about their work history and demographics and a survey about the services provided for each domestic violence survivor in their caseload that is a participant in the study (approximately 16 survivors per provider). This latter data collection will occur six months after a domestic violence survivor enrolls in the study over 15 months to correspond to the study enrollment period. Finally, the study will also include monthly data collection for 19 months from an agency point of contact (POC) in order to verify agency information (*e.g.,* the number of advocates working in the agency, advocate caseloads, dates of study participants' receipt of services).

Likely Respondents: The respondents are domestic violence survivors, primary service providers, and community agency points of contact who work with their agency data systems.

ANNUALIZED REPORTING BURDEN ON STUDY PARTICIPANTS

Form name	Type of respondent	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Time 1 (Baseline) Interview ..	Domestic violence survivors	256	1	1	256
Follow-up Interviews	Domestic violence survivors	256	2	1	512
Online survey about advocates' work history and demographics.	Victim service advocates	20	1	15/60	5
Online survey of advocates' work with survivors.	Victim service advocates	20	13	20/60	86
Form for community agency points of contact to verify agency information (monthly).	Community agency point of contact.	4	12	15/60	12
Total	.....	.....	.....	.....	871

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–29362 Filed 12–6–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Announcement for the Technical Advisory Panel on Medicare Trustee Reports

ACTION: Notice of public meeting.

SUMMARY: This notice announces the meeting dates for the Technical Advisory Panel on Medicare Trustee Reports on Monday, December 19, 2016 and Tuesday, December 20, 2016 in Washington, DC.

DATES: The meeting will be held on Monday, December 19, 2016 from 9:15 a.m. to 5:00 p.m. and Tuesday, December 20, 2016, from 9:00 a.m. to 3:30 p.m. Eastern Daylight Time (EDT) and it is open to the public.

ADDRESSES: The meeting will be held at the Hubert Humphrey Building, 200 Independence Ave. SW., Washington, DC 20201, Room 738G.3.

FOR FURTHER INFORMATION CONTACT: Dr. Donald Oellerich, Designated Federal Officer, at the Office of Human Services Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, (202) 690–8410.

SUPPLEMENTARY INFORMATION:

I. Purpose

The Panel will discuss the long-term rate of change in health spending and may make recommendations to the Secretary on how the Medicare Trustees might more accurately estimate health spending in the short and long run. The Panel's discussion is expected to be very technical in nature and will focus on the actuarial and economic assumptions and methods by which Trustees might more accurately measure health spending. This Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Committee is composed of nine members appointed by the Assistant Secretary for Planning and Evaluation.

II. Agenda

The Panel will likely hear presentations from two outside experts; one on prescription drugs spending and a second on spillover effects. In addition the HHS Office of the Actuary will present on issues the panel may wish to address. Additional presentations regarding long range growth, sustainability of provider payments under Affordable Care Act (ACA) and Medicare Access and Chip Reauthorization Act (MACRA), methods for transitioning from short term (10 year) to long term (75 year) projections and methods and the presentation of uncertainty in the report may follow. After any presentations, the Panel will deliberate openly on the topics. Interested persons may observe the deliberations, but the Panel will not hear public comments during this time. The Panel will also allow an open public session for any attendee to address issues specific to the topic.

III. Meeting Attendance

The Monday, December 19, 2016 and Tuesday, December 20, 2016 meetings are open to the public; however, in-person attendance is limited to space available.

Meeting Registration

The public may attend the meeting in-person. Space is limited and registration is *required* in order to attend in-person. Registration may be completed by emailing or faxing all the following information to Dr. Donald Oellerich at *don.oellerich@hhs.gov* or fax 202–690–6562:

Name.

Company name.

Postal address.

Email address.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Dr. Oellerich, no later than December 12, 2016 by sending an email message to *don.oellerich@hhs.gov* or calling 202–690–8410.

A confirmation email will be sent to the registrants shortly after completing the registration process.

IV. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

V. Copies of the Charter

The Secretary's Charter for the Technical Advisory Panel on Medicare Trustee Reports is available upon request from Dr. Donald Oellerich at *don.oellerich@hhs.gov* or by calling 202–690–8410.

Dated: December 2, 2016.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016–29331 Filed 12–6–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Financial Resources, Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Chapter AM, Office of the Assistant Secretary for Financial Resources (ASFR), as last amended at 78 FR 52197–52199 dated August 22, 2013; 76 FR19774–19776 dated April 8, 2011; 75 FR 369–370, dated January 5, 2010; 74 FR57679–57682, dated November 9, 2009; and 71 FR38884–88, dated July 10, 2006, as follows:

I. B. Under Section AM.20 Functions, make the following changes:

1. Under paragraph D, ''Office of Finance (AMS),'' delete in its entirety and replace with the following:

D. Chapter AMS, Office of Finance (AMS)

Section AMS.00 Mission: The Office of Finance (OF) is headed by the Deputy Assistant Secretary for Finance (DASF), who is also the Deputy Chief Financial Officer and reports to the Assistant Secretary for Financial Resources and Chief Financial Officer (CFO). The mission of the Office of Finance is to provide financial accountability and enhance program integrity through leadership, oversight, collaboration, and innovation.

The office includes the following:

- Immediate Office (AMS)
- Office of Financial Policy and Reporting (AMS1)
- Office of Financial Systems Policy and Oversight (AMS2)
- Office of Program Audit Coordination (AMS3)

1. *Immediate Office (AMS).* The Immediate Office (IO) is responsible for support and coordination to execute the mission of OF including implementation of HHS's Enterprise Risk Management (ERM) program. The Immediate Office includes:

- Division of Business Operations
- Division of Enterprise Risk Management

a. *Division of Business Operations.* The Division:

(1) Provides leadership for the HHS CFO community;

(2) Leads strategic planning for the HHS CFO community and the Office of Finance;

(3) Serves as the liaison with internal and external stakeholders regarding financial management matters;

(4) Provides operational support for the OF;

(5) Leads workforce development initiatives for the OF;

(6) Advises the ASFR/CFO regarding financial management matters affecting the Department; and

(7) Leads other activities that enhance OF's management and operations.

b. *Division of Enterprise Risk Management.* The Division:

(1) Coordinates across HHS to establish and communicate HHS's ERM vision, culture, strategy, and framework;

(2) Designs and implements an ERM infrastructure across HHS, including governance;

(3) Develops and shares tools, guidance, and best practices regarding ERM;

(4) Provides technical assistance and direction to HHS Operating Divisions (OPDIVs) and Staff Divisions (STAFFDIVs) on implementing ERM;

(5) Facilitates enterprise-wide, integrated and comprehensive assessments across HHS's risk portfolio including leading the development of the agency's risk profile and guiding management's prioritization of risks across the agency;

(6) Leads the Department's efforts to meet the ERM requirement in OMB Circular A–123, ''Management's Responsibility for Enterprise Risk Management and Internal Control'';

(7) Prepares reports, briefings, and makes recommendations to senior HHS leadership, OPDIVs, STAFFDIVs and other stakeholders on ERM related activities; and

(8) Leads other activities that enhance HHS implementation and integration of ERM into business operations.

2. *Office of Financial Policy and Reporting (AMS1).* The Office of Financial Policy and Reporting (OFPR) is responsible for financial management policy and standards, internal controls over reporting, statutory financial reports and audits, and other managerial reports. OFPR includes:

- Division of Financial Management Policy
- Division of Financial Statements and Audit
- Division of Financial Reporting and Analysis
- Division of Accounting Standardization and Oversight (AMS14)

a. *Division of Financial Management Policy.* The Division:

(1) Leads the Department's efforts to establish and maintain proper internal control over reporting and ensures that requirements are met under Appendix A, OMB Circular A–123, ''Management's Responsibility for Enterprise Risk Management and Internal Control'';

(2) Coordinates with the OPDIVs in the preparation of the corrective action plan (CAP), which is submitted annually to OMB and reflects the material weaknesses, significant deficiencies, and other reportable conditions from the annual CFO Act audit;

(3) Recommends, develops, and promulgates Department-wide policies, procedures, and standards for financial management areas including OMB, GAO, Treasury, Federal Accounting Standards Advisory Board (FASAB), and other agency guidance related to government-wide accounting policies and standards, cash management, credit management, debt management, payment and disbursement activities and functions, and budget execution accounting;

(4) Provides support to the OPDIV CFOs for financial planning and improvement initiatives;

(5) Serves as principal staff advisor on financial management policy matters to the DASF;

(6) Manages the Departmental process for the development of the required annual report on HHS's audited financial statements; and

(7) Maintains a system for tracking and improving cash and credit management and debt collection performance throughout the Department.

b. *Division of Financial Statements and Audit.* The Division:

(1) Oversees the preparation and submission of consolidated financial statements for the Department in accordance with OMB and Treasury requirements;

(2) Serves as the principal liaison with the Office of the Inspector General (OIG) in planning the annual financial statement audit strategy under the CFO Act, as amended. Coordinates with OPDIVs and STAFFDIVs to ensure timely audit deliverables;

(3) Reviews and interprets OMB, GAO, Treasury, and FASAB guidance and requirements related to government-wide accounting policies and standards;

(4) Assures that OPDIVs' reporting is in accordance with internal control and reporting standards from OMB, GAO, Treasury, FASAB, and the HHS Accounting Treatment Manual;

(5) Provides advice and assistance to OPDIVs and STAFFDIVs on financial reporting and related fiscal matters;

(6) Reviews and analyzes OPDIVs' financial statements and key reconciliations and consolidates Department financial statements as required by OMB and Treasury;

(7) Collaborates with the Division of Financial Management Policy on the preparation of the Department's agency financial report, CAPs and financial policies;

(8) Serves as the liaison with OMB, Treasury, intragovernmental groups and other agencies on accounting, financial policy and reporting issues; and

(9) Serves as the principal advisor to the DASF regarding financial reporting standards.

c. *Division of Financial Reporting and Analysis.* The Division:

(1) Oversees the design, preparation, and submission of financial management reports for the Department, as required by legislation, regulation, OMB, Treasury, GAO, and Congressional requests;

(2) Provides review and analysis of financial management reports for senior management, OMB, Treasury, GAO, Congress, and other stakeholders;

(3) Reviews and interprets OMB, GAO, Treasury, GAO, and FASAB guidance related to financial management reporting requirements or data requests that are in addition to the consolidated financial statements;

(4) Provides guidance, advice and assistance to OPDIVs and STAFFDIVs on new reporting requirements and related fiscal matters; and

(5) Serves as principal advisor to the DASF regarding new required financial management reports, and related OMB and Treasury transparency initiatives.

d. *Division of Accounting Standardization and Oversight.* The Division:

(1) Oversees the strategic planning and maintenance of the Department-wide Accounting Treatment Manual (ATM) in accordance with Federal accounting concepts, standards, and HHS financial management policies;

(2) Establishes developmental goals that promote improvement within the ATM framework and support the Department-wide standardization of accounting data elements and related attributes;

(3) Monitors financial data for adherence to Department-wide accounting standards, and advises OPDIVs on proper accounting treatments in accordance with the Department's ATM;

(4) Introduces uniform business rules and data standards required to support new financial reporting requirements;

(5) Collaborates with system owners and financial management offices to facilitate standardized enterprise-wide solutions within the financial accounting and reporting systems;

(6) Serves as liaison with OMB, Treasury, and other authoritative Federal agencies on standard general ledger compliance matters;

(7) Collaborates with the Office of Financial Systems Policy and Oversight to ensure financial system conformity with the ATM and related data standards; and

(8) Serves as principal staff advisor to the DASF as it relates to proper accounting treatment, accounting standardization, and financial performance monitoring.

3. *Office of Financial Systems Policy and Oversight (AMS2).* The Office of Financial Systems Policy and Oversight (OFSPO) is responsible for overseeing the Department-wide financial systems. This includes developing and managing the Department-wide financial systems policy, governance, and program and systems management. OFSPO is also responsible for maintaining the Department-wide systems including the Unified Financial Management System (UFMS), the Financial Business Intelligence System (FBIS), and the Consolidated Financial Reporting System (CFRS). OFSPO includes:

- Division of Strategic Planning, Oversight and Coordination
- Division of Budget and Acquisition
- Division of Program Management and Governance
- Division of Systems Policy and Compliance
- Division of Systems Planning and Development
- Division of Systems Operations and Maintenance

a. *Division of Strategic Planning, Oversight and Coordination.* The Division:

(1) Provides oversight of all aspects of the Department-wide financial systems and coordinates with executive-level stakeholders to execute the financial systems strategy;

(2) Supports and coordinates the other OFSPO divisions in management of designated functions and responsibilities;

(3) Develops strategic plans to manage, enhance and support the Department-wide financial systems environment;

(4) Serves as the liaison with internal and external stakeholders regarding financial systems;

(5) Advises the DASF regarding financial systems matters affecting the Department.

b. *Division of Budget and Acquisition.* The Division:

(1) Prepares and manages the budget for OF-managed financial systems;

(2) Manages the IT portfolio and investment functions throughout the Capital Planning & Investment Control Lifecycle (CPIC) for OF-managed financial systems;

(3) Establishes and manages acquisition vehicles for Department-wide financial systems, including contract management and program monitoring; and,

(4) Ensures that services are aligned with changing business needs and improvements are made to processes, IT services, and IT infrastructure.

c. *Division of Program Management and Governance.* The Division:

(1) Oversees the Department-wide financial systems, including the three major core accounting systems (the Healthcare Integrated General Ledger Accounting System (HIGLAS) at the Centers for Medicare & Medicaid Services (CMS), National Institutes of Health Business System (NBS), and the Unified Financial Management System (UFMS) for the rest of the Department), the Consolidated Financial Reporting System (CFRS), and the Financial Business Intelligence System (FBIS);

(2) Establishes, facilitates, and supports a governance framework for Department-wide financial management;

(3) Provides project management and strategic communications support for financial systems and programs;

(4) Reports financial system program and project performance (progress, milestones, risks, etc.) to HHS financial management leadership and customers on a periodic basis; and

(5) Maintains and analyzes service level metrics for provided services.

d. *Division of Systems Policy and Compliance.* The Division:

(1) Develops policies for Department-wide financial management systems including core financial systems and the financial portion of the mixed systems;

(2) Oversees compliance with Federal and Departmental policies and procedures for financial systems, including compliance with the Federal Financial Management Improvement Act of 1996 (FFMIA) and Section 4 of the Federal Managers' Financial Integrity Act (FMFIA);

(3) Oversees development, maintenance, and execution of

corrective action plans for Department-wide financial systems to remediate security vulnerabilities and audit findings;

(4) Collaborates with the HHS Office of the Chief Information Officer (OCIO) and ensures that financial systems security controls are comprehensive, effective, and efficient; and

(5) Provides oversight of the security controls environment for OF-managed financial systems.

e. *Division of Systems Planning and Development.* The Division:

(1) Performs the planning, design, development, and implementation of Department-wide financial systems, including UFMS, CFRS and FBIS;

(2) Coordinates activities to enhance the Department-wide financial systems environment;

(3) Collaborates with other business domains to integrate mixed financial systems;

(4) Identifies and plans for the integration of new technologies and programs into the financial systems environment, based on analysis of industry trends, best practices, and current/future business requirements; and

(5) Administers a data governance program, including supporting the implementation of Department-wide financial definitions and data structures.

f. *Division of Systems Operations and Maintenance.* The Division:

(1) Provides comprehensive IT service management (operations and maintenance) for Department-wide financial systems, including UFMS, CFRS, FBIS, and other business systems, and ensures the applications are secure, reliable, and available;

(2) Coordinates and executes the activities and processes required to deliver and manage services at agreed levels to business users and customers;

(3) Manages the technology that is used to deliver and support services; and

(4) Manages activities to resolve security vulnerabilities and audit findings identified within the managed systems.

4. *Office of Program Audit Coordination (AMS3).* The Office of Program Audit Coordination (OPAC) serves as the central point of contact for coordinating program audit support through payment accuracy and audit resolution activities across the Department. The Office includes:

- Division of Payment Integrity Improvement
- Division of Audit Resolution
- Division of Audit Tracking and Analysis

a. *Division of Payment Integrity Improvement.* The Division:

(1) Implements the Improper Payments Information Act of 2002, the Improper Payments Elimination and Recovery Act of 2010, the Improper Payments Elimination and Recovery Improvement Act of 2012, and improper payment related Executive Orders and other regulatory requirements;

(2) Provides analysis of high risk programs and coordinates error rate measurements and CAPs for high risk programs;

(3) Coordinates efforts among OPDIVs to recapture improper payments;

(4) Identifies and shares best practices on addressing improper payments with HHS leadership;

(5) Coordinates implementation of the ''Do Not Pay'' initiative at HHS;

(6) Prepares reports and briefings, and makes recommendations to senior HHS leadership, OPDIVs, OMB and other stakeholders on improper payment initiatives; and

(7) Leads other activities that support improving payment accuracy.

b. *Division of Audit Resolution.* The Division:

(1) Reviews, resolves, and coordinates, where necessary, the single audit findings of grantees affecting the programs of more than one OPDIV or other Federal agency;

(2) Coordinates and provides technical assistance to grantees and HHS Divisions on all aspects of single audit resolution in an effort to reduce the number and significance of single audit findings;

(3) Works with HHS's Single Audit Coordinator to streamline and enhance the efficiency of the audit resolution process;

(4) Interprets single audit guidance and establishes and monitors Department policies regarding audit resolution and associated metrics and analytics;

(5) Prepares reports, briefings, and makes recommendations to senior HHS leadership, OPDIVs, and other stakeholders regarding single audit resolution activities;

(6) Prepares the Management Report on Final Action;

(7) Ensures HHS compliance with the Uniform Guidance (2 CFR part 200); and

(8) Leads other activities that support and advance audit resolution.

c. *Division of Audit Tracking and Analysis.* The Division:

(1) Develops, implements, and manages an enterprise-wide audit tracking and analytics system that includes at a minimum: single audits, OIG audits, and GAO audits;

(2) Oversees and coordinates Department-wide change management efforts to prepare OPDIVs for implementation and future changes to the enterprise-wide system;

(3) Provides operations and maintenance support for the enterprise-wide system;

(4) Assigns single audit findings to OPDIVs and STAFFDIVs for resolution;

(5) Ensures HHS' single audit findings are resolved in accordance with the guidelines promulgated in the Uniform Guidance (2 CFR part 200);

(6) Performs analysis on audit data to assist in targeting corrective actions and reducing future findings; and

(7) Leads other activities that support the implementation of the enterprise-wide system and usage of the data maintained in the system.

II. Delegations of Authority. All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegation, provided they are consistent with this reorganization.

Dated: November 30, 2016.

Colleen Barros,

Acting Assistant Secretary for Administration.

[FR Doc. 2016–29332 Filed 12–6–16; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Behavioral Health, Office of Clinical and Preventive Services; Methamphetamine and Suicide Prevention Initiative—Generation Indigenous (Gen–I) Initiative Support

Announcement Type: New.

Funding Announcement Number: HHS–2017–IHS–MSPI–0001.

Catalog of Federal Domestic Assistance Number (CFDA): 93.933.

Key Dates

Application Deadline Date: January 9, 2017.

Review Date: January 17–27, 2017.

Earliest Anticipated Start Date: February 15, 2017.

Signed Tribal Resolutions Due Date: January 9, 2017.

Proof of Non-Profit Status Due Date: January 9, 2017.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), an agency which is part of the Department of Health and Human Services (HHS), is accepting applications for grants for the

Methamphetamine and Suicide Prevention Initiative (Short Title: MSPI)—Generation Indigenous (GEN–I) Initiative Support to continue the planning, development and implementation of the current grant funding cycle for the MSPI Purpose Area #4 (GEN–I Initiative Support) that focuses on promoting early intervention strategies and the implementation of positive youth development programming to reduce risk factors for suicidal behavior and substance abuse by working with Native youth up to and including age 24. This program was first established by the Consolidated Appropriations Act of 2008, Public Law 110–161, 121 Stat. 1844, 2135, and has been continued in the annual appropriations acts since that time. This program is authorized under the authority of the Snyder Act, 25 U.S.C. 13 and the Indian Health Care Improvement Act, 25 U.S.C. 1601–1683. The amounts made available for MSPI funding shall be allocated at the discretion of the Principal Deputy Director of IHS and shall remain available until expended. IHS utilizes a national funding formula developed in consultation with Tribes and the National Tribal Advisory Committee on behavioral health, as well as conferring with urban Indian organizations (UIOs). The funding formula provides the allocation methodology for each IHS service area. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The overall goals of MSPI are to: (1) Increase Tribal, UIO, and Federal capacity to operate successful methamphetamine prevention, treatment, and aftercare and suicide prevention, intervention, and postvention services through implementing community and organizational needs assessment and strategic plans; (2) develop and foster data sharing systems among Tribal, UIO, and Federal behavioral health service providers to demonstrate efficacy and impact; (3) identify and address suicide ideations, attempts, and contagions among American Indian and Alaska Native (AI/AN) populations through the development and implementation of culturally appropriate and community relevant prevention, intervention, and postvention strategies; (4) identify and address methamphetamine use among AI/AN populations through the development and implementation of culturally appropriate and community relevant prevention, treatment, and aftercare strategies; (5) identify provider and community education on suicide and methamphetamine use by offering appropriate trainings; and (6) promote positive AI/AN youth development and family engagement through the implementation of early intervention strategies to reduce risk factors for suicidal behavior and substance abuse.

Purpose

The primary purpose of this IHS grant is to focus on MSPI goal #6, ''to promote positive AI/AN youth development and family engagement through the implementation of early intervention strategies to reduce risk factors for suicidal behavior and substance use.'' Grants will be awarded in three IHS Areas: Navajo Area, Phoenix Area, and the Tucson Area. The last FOA did not yield the full allocation of funds for these three IHS Areas. Projects will accomplish this by focusing specifically on MSPI Purpose Area #4: GEN–I Initiative Support.

Purpose Area #4: Generation Indigenous Initiative Support

The focus of Purpose Area #4 is to:

1. Implement evidence-based and practice-based approaches to build resiliency, promote positive development, and increase self-sufficiency behaviors among Native youth;
2. Promote family engagement;
3. Increase access to prevention activities for youth to prevent methamphetamine use and other substance use disorders that contribute to suicidal behaviors, in culturally appropriate ways; and
4. Hire additional behavioral health staff (*i.e.,* licensed behavioral health providers and paraprofessionals, including but not limited to peer specialists, mental health technicians, and community health aides) specializing in child, adolescent, and family services who will be responsible for implementing the project's activities that address all the broad objectives listed.

All four of the broad objectives listed for MSPI Purpose Area #4 must be addressed in the application Project Narrative scope of work for new applicants. If an application submission does not address all the required broad objectives in the Project Narrative scope of work, the application will not be considered for funding.

Evidence-Based Practices, Practice-Based Evidence, Promising Practices, and Local Efforts

IHS strongly emphasizes the use of data and evidence in policymaking and program development and implementation. Applicants must identify one or more evidence-based practice, practice-based evidence, best or promising practice, and/or local effort that the applicant plans to implement in the Project Narrative section of the application. The MSPI Program Web site (*http://www.ihs.gov/mspi/bestpractices/*) is one resource that applicants may use to find information to build on the foundation of prior substance use and suicide prevention and treatment efforts in order to support the IHS and Tribes in developing and implementing Tribal and/or culturally appropriate substance use and suicide prevention and early intervention strategies.

Pre-Conference Grant Requirements

This section is only required if the applicant has included a ''conference'' in the proposed scope of work and intends on using funding to plan and conduct a conference or meeting during the project period. For definitions of what constitutes a ''conference,'' please see the policy at the link provided below. The awardee is required to comply with the ''HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications,'' dated December 16, 2013 (''Policy''), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at *http://www.hhs.gov/grants/contracts/contract-policies-regulations/conference-spending/.*

The awardee is required to:

Provide a separate detailed budget justification and narrative for each conference anticipated. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, and (8) Other (explain in detail and cost breakdown). For additional questions please contact Audrey Solimon, National Program Coordinator in the IHS Division of Behavioral Health, at *Audrey.Solimon@ihs.gov.*

II. Award Information

Type of Award

Grant.

Estimated Funds Available

The total amount of funding identified for awards is approximately $1,417,142 for all three IHS areas. Applicants will be awarded according to their location within their respective IHS service area and will not compete

with applicants from other IHS service areas. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately six awards will be issued under this funding opportunity announcement. The funding breakdown by area is as follows:

Navajo IHS Service Area

IHS expects to provide approximately $819,142 in total awards. Applicants may apply for amounts between $200,000–$400,000, or, if applying on behalf of the entire Tribe, IHS will accept applications for the entire award amount of $819,142.

Phoenix IHS Service Area

IHS expects to provide approximately $525,000 in total awards. Applicants should apply for $175,000.

Tucson IHS Service Area

IHS expects to make one award in the amount of $73,000. Applicants should apply for $73,000.

Project Period

The period of performance for this funding announcement will be for four years. Applicants should note that the first budget period will run from February 1, 2017 to September 29, 2017 (the first budget period will only be for 7 months, but a full 12 months of funding will be provided). Budget periods 2–4 will be for a 12 month period and run consecutively from September 30, 2017 to September 29, 2020.

III. Eligibility Information

1. Eligibility

Eligible applicants must be one of the following as defined by 25 U.S.C. 1603:

- A Federally-recognized Indian Tribe 25 U.S.C. 1603(14).
- A Tribal organization 25 U.S.C. 1603(26).

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If an application's budget exceeds the maximum funding amount listed for the applicant's IHS area breakdown outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Grantee/Awardee Meetings

Grantees/awardees are required to send the project director and/or project coordinator (the individual who runs the day-to-day project operations) to an annual MSPI meeting. Participation will be in-person or via virtual meetings. The grantee/awardee is required to include travel for this purpose in the budget and narrative of the project proposal. At these meetings, grantees/awardees will present updates and results of their projects including note of significant or ongoing concerns related to project implementation or management. Federal staff will provide updates and technical assistance to grantees/awardees in attendance.

Tribal Resolution

Tribal resolutions are required from all Tribes and Tribal organizations. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include *resolutions from all affected Tribes to be served.* Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

An official signed Tribal resolution must be received by the DGM prior to a Notice of Award being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, a draft Tribal resolution must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a Notice of Award will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the grants management specialist listed in this funding announcement.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS DGM by obtaining documentation confirming delivery (*i.e.,* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of Contents.
- Abstract (must be single-spaced and not exceed one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Statement of Need (must be single-spaced and not exceed two pages).
  - Includes the Tribe or Tribal organization background information.
- Project Narrative (must be single-spaced and not exceed 20 pages).
  - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeline Chart, and a Local Data Collection Plan.
- Budget and Budget Narrative (must be single-spaced and not exceed four pages).

- Tribal Resolution(s) (only required for Indian Tribes and Tribal organizations).
- Letter(s) of Support:
  - *For all applicants:* local organizational partners;
  - *For all applicants:* community partners;
  - *For Tribal organizations:* from the board of directors (or relevant equivalent);
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all key personnel (*e.g.,* project director, project coordinator, grants coordinator, etc.).
- Contractor/consultant qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: *https://harvester.census.gov/facdissem/Main.aspx.*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.

Requirements for Statement of Need

The statement of need describes the history and current situation in the applicant's Tribal community (''community'' means the applicant's Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). The statement of need provides the facts and evidence that support the need for the project and establishes that the Tribe or Tribal organization understands the problems and can reasonably address them and provides background information on the Tribe or Tribal organization. The statement of need must not exceed two single-spaced pages and must be type written, have consecutively number pages, use black type not smaller than 12 point, and printed on one side of standard size 8-1/2″ × 11″ paper.

Requirements for Project, Budget and Budget Narratives

A. *Project Narrative:* This narrative, or proposed approach, should be a separate Word document that is no longer than 20 pages and must: be single-spaced, type written, have consecutively numbered pages, use black type not smaller than 12 points, and be printed on one side only of standard size 8-1/2″ x 11″ paper.

Be sure to succinctly address and answer all questions listed under the Project Narrative section and place them under the evaluation review criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first 20 pages will be reviewed. The 20-page limit for the narrative does not include the table of contents, abstract, statement of need, work plan, standard forms, Tribal resolutions, budget or budget narrative, and/or other appendix items.

There are five (5) parts to the project narrative:

- Part A—Goals and Objectives;
- Part B—Project Activities;
- Part C—Timeline Chart (template provided);
- Part D—Organizational Capacity and Staffing/Administration; and
- Part E—Plan for Local Data Collection.

See below for additional details about what must be included in the narrative.

Part A: Goals and Objectives

- Describe the purpose of the proposed project that includes a clear statement of goals and objectives.
- Address the four (4) broad objectives listed for MSPI Purpose Area #4 and the objectives should be clearly outlined in the project narrative. If the application does not address all four broad objectives, the application will be considered ineligible and will not be reviewed for further consideration.

Part B: Project Activities

- Describe how project activities will increase the capacity of the identified community to plan and improve the coordination of a collaborative behavioral health and wellness service systems.
- Describe anticipated barriers to progress of the project and how the barriers will be addressed.
- Discuss how the proposed approach addresses the local language, concepts, attitudes, norms and values about suicide, and/or substance use.
- Describe how the proposed project will address issues of diversity within the population of focus including age, race, gender, ethnicity, culture/cultural identity, language, sexual orientation, disability, and literacy.
- If the applicant plans to include an advisory body in the project, describe its membership, roles and functions, and frequency of meetings.
- Describe how the efforts of the proposed project will be coordinated with any other related Federal grants, including IHS, the Substance Abuse and Mental Health Services Administration (SAMHSA), or Bureau of Indian Affairs (BIA) services provided in the community (if applicable).
- Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include a list of these organizations as an *attachment* to the application. In the attached list, indicate the organizations that the Tribe or Tribal organization has worked with or currently works with. [Note: The attachment will not count as part of the 20-page maximum].

Part C: Timeline Chart

- Provide a one-year (first budget year) timeline chart depicting a realistic timeline for the project period showing key activities, milestones, and responsible staff. These key activities should include the requirements outlined for MSPI Purpose Area #4. [**Note:** The timeline chart should be included as part of the Project Narrative as specified here. It should not be placed as an attachment.]. The timeline chart should not exceed one page.

Part D: Organizational Capacity and Staffing/Administration

- Describe the management capability and experience of the applicant Tribe or Tribal organization and other participating organizations in administering similar grants and projects.
- Discuss the applicant Tribe or Tribal organization experience and capacity to provide culturally appropriate/competent services to the community and specific populations of focus.
- Describe the resources available for the proposed project (*e.g.,* facilities, equipment, information technology systems, and financial management systems).
- Describe how project continuity will be maintained if/when there is a change in the operational environment (*e.g.,* staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

• Provide a complete list of staff positions for the project, including the project director, project coordinator, and other key personnel, showing the role of each and their level of effort and qualifications.

• Include position descriptions as *attachments* to the project proposal/application for the project director, project coordinator, and all key personnel. Position descriptions should not exceed one page each. [**Note:** Attachments will not count against the 20 page maximum].

• For individuals that are identified and currently on staff, include a biographical sketch (not to include personally identifiable information) for the project director, project coordinator, and other key positions as *attachments* to the project proposal/application. Each biographical sketch should not exceed one page. Reviewers will not consider information past page one. [**Note:** Attachments will not count against the 20 page maximum]. *Do not* include any of the following:

▪ Personally Identifiable Information;
▪ Resumes; or
▪ Curriculum Vitae.

Part E: Plan for Local Data Collection

• Describe the applicant's plan for gathering local data, submitting data requirements, and document the applicant's ability to ensure accurate data tracking and reporting. Describe how members of the community (including youth and families that may receive services) will be involved in the planning, implementation, and data collection.

Funded projects are required to coordinate data collection efforts with their assigned regional Technical Assistance (TA) Provider for evaluation. The regional TA Providers for evaluation are the Tribal Epidemiology Centers (TECs) for each IHS area. The TA Providers for evaluation are funded by IHS. Awardees will work with their assigned regional TA Provider for evaluation to measure and track the core processes, outcomes, impacts, and benefits associated with the MSPI. Awardees shall collect local data related to the project and submit it in annual progress reports to IHS and will assist the national MSPI evaluation. The purpose of the national evaluation is to assess the extent to which the projects are successful in achieving project goals and objectives and to determine the impact of MSPI-related activities on individuals and the larger community.

Progress reporting will be required on national data elements related to program outcomes and financial reporting for all awardees. Progress reports will be collected annually throughout the project on a Web-based data portal and transferred to the GrantSolutions system to comply with the grant requirements. Progress reports include the compilation of quantitative (numerical) data (*e.g.,* number served, screenings completed, etc.) and qualitative or narrative (text) data (*e.g.,* program accomplishments, barriers to implementation, and description of partnership and coalition work).

The reporting portal will be open to project staff on a 24 hour/7 day week basis for the duration of each reporting period. In addition, Federal financial report forms (SF–425), which document funds received and expended during the reporting period, will be available. Required financial forms will be available from the IHS DGM, and other required forms will be provided throughout the funding period by DGM or the IHS Division of Behavioral Health (DBH). All document/materials are to be submitted online. Technical assistance for Web-based data entry and for the completion of required fiscal documents will be timely and readily available to awardees by assigned IHS area project officers.

B. *Budget and Budget Narrative:* The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for Budget Year 1 only. The budget should match the scope of work described in the project narrative for the first budget year expenses only. The page limitation should not exceed four single-spaced pages.

The applicant must provide a narrative justification for all items included in the proposed line item budget supporting the mission and goals of MSPI, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-Federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions or non-Federal means. (This should correspond to Item #18 on the applicant's SF–424, Estimated Funding.) Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

Templates

Templates are provided for the project narrative, timeline chart, budget and budget narrative, and biographical sketch. These templates can be located and downloaded at the MSPI Web site at: *https://www.ihs.gov/mspi.*

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

• Pre-award costs are not allowable.
• The available funds are inclusive of direct and appropriate indirect costs.
• Only one grant/cooperative agreement will be awarded per applicant.
• IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the ''Find Grant Opportunities'' link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a

waiver must be requested. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* The waiver must (1) be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Senior Policy Analyst of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor the DBH will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS grants management, grants policy Web site: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 20 page narrative should include only the first year of activities. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

1. Criteria

Applications will be reviewed and scored according to the quality of responses to the required application components in Sections A–E below. In developing the required sections of this application, use the instructions provided for each section, which have been tailored to this program. The application must use the five sections (Sections A–E) listed below in developing the application. The applicant must place the required information in the correct section or it will not be considered for review. The application will be scored according to how well the applicant addresses the requirements for each section listed below. The number of points after each heading is the maximum number of points the review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed deriving the overall section score.

A. Statement of Need (History and Current Situation in your Tribal Community) (35 points)

The statement of need should not exceed two single-spaced pages.

(1) Identify the proposed catchment area and provide demographic information on the population(s) to receive services through the targeted systems or agencies, *e.g.,* race, ethnicity,

Federally recognized Tribe, language, age, socioeconomic status, sexual identity (sexual orientation, gender identity), and other relevant factors, such as literacy. Describe the stakeholders and resources in the catchment area that can help implement the needed infrastructure development.

(2) Based on the information and/or data currently available, document the prevalence of suicide ideations, attempts, clusters (groups of suicides or suicide attempts or both that occurred close together in time and space), and completions, and substance use rates. For this purpose area, the data should be geared toward AI/AN children and youth.

(3) Based on the information and/or data currently available, document the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective substance abuse prevention and/or behavioral health services in the proposed catchment area that is consistent with the purpose of the program and the funding opportunity announcement. Based on available data, describe the service gaps and other problems related to the need for infrastructure development. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are local epidemiologic data (TECs, IHS area offices), state data (*e.g.,* from state needs assessments), and/or national data (*e.g.,* SAMHSA's National Survey on Drug Use and Health or from National Center for Health Statistics/Centers for Disease Control reports, and census data). This list is not exhaustive; applicants may submit other valid data, as appropriate for the applicant's program.

(4) Describe the current suicide prevention, substance abuse prevention, trauma-related, and mental health promotion activities happening in the applicant's community/communities for Native youth up to and including age 24 and their families. Indicate which organizations/entities are currently offering these activities and where the resources come from to support them.

(5) Describe the current service gaps, including disconnection between available services and unmet needs of Native youth up to and including age 24 and their families.

(6) Describe potential project partners and community resources in the catchment area that can participate in the planning process and infrastructure development.

B. Project Narrative/Proposed Approach (20 points)

The project narrative required components (listed as the six components in ''Requirements for Project Narrative'') together should not exceed 20 single-spaced pages.

(1) Describe the purpose of the proposed project, including a clear statement of goals and objectives. The proposed project narrative is required to address all four objectives listed for MSPI Purpose Area #4. Describe how achievement of goals will increase system capacity to support the goals and objectives or activities for MSPI Purpose Area #4 by showing how the project will work with Native youth up to and including age 24.

(2) Describe how project activities will increase the capacity of the identified community to plan and improve the coordination of a collaborative behavioral health and wellness service systems. Describe anticipated barriers to progress of the project and how these barriers will be addressed.

(3) Discuss how the proposed approach addresses the local language, concepts, attitudes, norms and values about suicide, and/or substance use.

(4) Describe how the proposed project will address issues of diversity for Native youth up to and including age 24 including race/ethnicity, gender, culture/cultural identity, language, sexual orientation, disability, and literacy.

(5) Describe how Native youth up to and including ages 24 and families may receive services and how they will be involved in the planning, implementation, and data collection and regional evaluation of the project.

(6) Describe how the efforts of the proposed project will be coordinated with any other related Federal grants, including IHS, SAMHSA, or BIA services provided in the community (if applicable).

(7) Provide a timeline chart depicting a realistic timeline for the 1-year project period showing key activities, milestones, and responsible staff. [Note: The timeline chart should be part of the project narrative as specified in the ''Requirements for Project Proposals'' section. It should not be placed as an attachment.]

(8) If the applicant plans to include an advisory body in the project, describe its membership, roles and functions, and frequency of meetings.

(9) Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include a list of these organizations as an *attachment* to the project proposal/application. In the attached list, indicate the organizations that the Tribe or Tribal organization has worked with or currently works with. [**Note:** The attachment will not count as part of the 20-page maximum.]

C. Organizational Capacity and Staffing/Administration (15 points)

(1) Describe the management capability and experience of the applicant Tribe or Tribal organization and other participating organizations in administering similar grants and projects.

(2) Identify the department/division that will administer this project. Include a description of this entity, its function and its placement within the organization (Tribe or Tribal organization). If the program is to be managed by a consortium or Tribal organization, identify how the project office relates to the member community/communities.

(3) Discuss the applicant Tribe or Tribal organization experience and capacity to provide culturally appropriate/competent services to the community and specific populations of focus.

(4) Describe the resources available for the proposed project (*e.g.,* facilities, equipment, information technology systems, and financial management systems).

(5) Describe how project continuity will be maintained if/when there is a change in the operational environment (*e.g.,* staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

(6) Provide a list of staff positions for the project, including the behavioral health staff, project director, project coordinator, and other key personnel, showing the role of each and their level of effort and qualifications. Demonstrate successful project implementation for the level of effort budgeted for the behavioral health staff, project director, project coordinator, and other key staff.

(7) Include position descriptions as *attachments* to the application for the behavioral health staff, project director, project coordinator, and all key personnel. Position descriptions should not exceed one page each. [**Note:** Attachments will not count against the 20 page maximum.]

(8) For individuals that are currently on staff, include a biographical sketch (not to include personally identifiable information) for each individual that will be listed as the behavioral health

staff, project director, project coordinator, and other key positions. Describe the experience of identified staff in mental health promotion, suicide and substance abuse prevention work in the community/communities. Include each biographical sketch as *attachments* to the project proposal/application. Biographical sketches should not exceed one page per staff member. Reviewers will not consider information past page one. [**Note:** Attachments will not count against the 20 page maximum.] *Do not* include any of the following:

- Personally Identifiable Information;
- Resumes; or
- Curriculum Vitae.

D. Local Data Collection Plan (20 points)

Describe the applicant's plan for gathering local data, submitting data requirements, and document the applicant's ability to ensure accurate data tracking and reporting. Describe how members of the community (including Native youth up to and including age 24 and families that may receive services) will be involved in the planning, implementation, and data collection.

Funded projects are required to coordinate data collection efforts with their assigned regional TA Provider for evaluation. The regional TA Providers for evaluation are the TECs for each IHS area. The TA Providers for evaluation are funded by IHS. Awardees will work with their assigned regional TA Provider for evaluation to measure and track the core processes, outcomes, impacts, and benefits associated with the MSPI. Awardees shall collect local data related to the project and submit it in annual progress reports to IHS and will assist the national MSPI evaluation. The purpose of the national evaluation is to assess the extent to which the projects are successful in achieving project goals and objectives and to determine the impact of MSPI-related activities on individuals and the larger community.

Progress reporting will be required on national selected data elements related to program outcomes and financial reporting for all awardees. Progress reports will be collected annually throughout the project on a web-based data portal. Progress reports include the compilation of quantitative (numerical) data (*e.g.,* number served, screenings completed, etc.) and qualitative or narrative (text) data (*e.g.,* program accomplishments, barriers to implementation, and description of partnership and coalition work).

E. Budget and Budget Narrative (10 points)

The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for Budget Year 1 only. The budget should match the scope of work described in the project narrative for the first budget year expenses only. The budget and budget narrative must not exceed four single-spaced pages.

The applicant must provide a narrative justification of the items included in the proposed line item budget supporting the mission and goals of MSPI, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-Federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions or non-Federal means (this should correspond to Item #18 on the applicant's SF–424, Estimated Funding). Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

The Budget and Budget Narrative the applicant provides will be considered by reviewers in assessing the applicant's submission, along with the material in the Project Narrative. Applicants should ensure that the budget and budget narrative are aligned with the project narrative.

Additional Documents Can Be Uploaded as Appendix Items in *Grants.gov*

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF–424) of the application. The IHS program office will also provide additional contact information

as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved'', but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of fiscal year 2017, the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Grants are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the indirect cost policy, please call the grants management specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final program progress report must be submitted within 90 days of expiration of the budget/project period at the end of the funding cycle. Additional information for reporting and associated requirements will be included in the ''Programmatic Terms and Conditions'' in the official NoA, if funded.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at *http://www.dpm.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the grants management specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Post Conference Grant Reporting

This section is only required if the applicant has included a ''conference'' in the proposed scope of work and intends on using funding to plan and conduct a conference or meeting during the project period. The following requirements were enacted in Section 3003 of the Consolidated Continuing Appropriations Act, 2013, and Section 119 of the Continuing Appropriations Act, 2014; *Office of Management and Budget Memorandum M–12–12:* All HHS/IHS awards containing grants funds allocated for conferences will be required to complete a mandatory post award report for all conferences. Specifically: The total amount of funds provided in this award/cooperative agreement that were spent for ''Conference X'' must be reported in final detailed actual costs *within 15 days of the completion of the conference.* Cost categories to address should be: *(1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, and (8) Other.*

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and

Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *http://www.ihs.gov/dgm/policytopics/.*

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS OCR for more information about obligations and prohibitions under Federal civil rights laws at *http://www.hhs.gov/ocr/about-us/contact-us/headquarters-and-regional-addresses/index.html* or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857 (Include ''Mandatory Grant Disclosures'' in subject line).

Office: (301) 443–5204.

Fax: (301) 594–0899.

Email: Robert.Tarwater@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201.

URL: http://oig.hhs.gov/fraud/report-fraud/index.asp (Include ''Mandatory Grant Disclosures'' in subject line).

Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or

Email: MandatoryGrantee Disclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Audrey Solimon, Public Health Analyst, National MSPI/DVPI Program Coordinator, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N34–A, Rockville, MD 20857.

Phone: (301) 590–5421.

Fax: (301) 594–6213.

Email: Audrey.Solimon@ihs.gov.

2. *Questions on grants management and fiscal matters may be directed to:*

Donald Gooding, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857.

Phone: (301) 443–2298.

Fax: (301) 594–0899.

Email: Gooding.Donald@ihs.gov.

3. *Questions on systems matters may be directed to:* Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857.

Phone: (301) 443–2114; or the DGM main line (301) 443–5204.

Fax: (301) 594–0899. *E-Mail: Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: November 29, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016–29262 Filed 12–6–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable 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, Structural Correlates of Prestin Activity.

Date: December 21, 2016.

Time: 1:00 p.m. to 3:00 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: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, *jdrgonova@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 1, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–29266 Filed 12–6–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2016–0015)

The Critical Infrastructure Partnership Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Quarterly Critical Infrastructure Partnership Advisory Council membership update.

SUMMARY: The Department of Homeland Security (DHS) announced the establishment of the Critical Infrastructure Partnership Advisory Council (CIPAC) in a **Federal Register** Notice (71 FR 14930–14933) dated March 24, 2006, which identified the purpose of CIPAC, as well as its membership. This notice provides: (i) Quarterly CIPAC membership updates; (ii) instructions on how the public can obtain the CIPAC membership roster and other information on the council; and (iii) information on recently completed CIPAC meetings.

FOR FURTHER INFORMATION CONTACT: Renee Murphy, Designated Federal Officer, Critical Infrastructure Partnership Advisory Council, Sector Outreach and Programs Division, Office of Infrastructure Protection, National Protection and Programs Directorate, U.S. Department of Homeland Security, 245 Murray Lane, Mail Stop 0607, Arlington, VA 20598–0607; telephone: (703) 603–5083; email: *CIPAC@hq.dhs.gov.*

Responsible DHS Official: Renee Murphy, Designated Federal Officer for CIPAC.

SUPPLEMENTARY INFORMATION:

Purpose and Activity: The CIPAC facilitates interaction between government officials and representatives of the community of owners and/or operators for each of the critical infrastructure sectors defined by Presidential Policy Directive 21 and identified in *National Infrastructure Protection Plan 2013: Partnering for Critical Infrastructure Security and Resilience.* The activities covered by the CIPAC include: Planning; coordinating among government and critical infrastructure owner and operator partners; implementing security and resilience program initiatives; conducting operational activities related to critical infrastructure security and resilience measures, incident response and recovery; reconstituting critical infrastructure assets and systems from manmade and naturally occurring events; sharing threat, vulnerability, risk mitigation, and business continuity information; and distributing best practices and lessons learned at the classified and unclassified levels.

Organizational Structure: CIPAC members are organized into 16 critical infrastructure sectors. These sectors have a Government Coordinating Council whose membership includes: (i) A lead Federal agency that is defined as the Sector-Specific Agency; (ii) all relevant Federal, State, local, tribal, and/or territorial government agencies (or their representative bodies) whose mission interests also involve the scope of the CIPAC activities for that particular sector; and (iii) a Sector Coordinating Council (SCC), where applicable, whose membership includes critical infrastructure owners and/or operators or their representative trade associations.

CIPAC Membership: CIPAC Membership may include:

(i) Critical Infrastructure owner and operator members of a DHS-recognized SCC, including their representative trade associations or equivalent organization members of a SCC as determined by the SCC.

(ii) Federal, State, local, and tribal governmental entities comprising the members of the GCC for each sector, including their representative organizations; members of the State, Local, Tribal, and Territorial Government Coordinating Council; and representatives of other Federal agencies with responsibility for Critical Infrastructure activities.

CIPAC membership is organizational. Multiple individuals may participate in CIPAC activities on behalf of a member organization.

CIPAC Membership Roster and Council Information: The current roster of CIPAC members is published on the CIPAC Web site (*http://www.dhs.gov/cipac*) and is updated as the CIPAC membership changes. Members of the public may visit the CIPAC Web site at any time to view current CIPAC membership, as well as the current and historic lists of CIPAC meetings and agendas.

Dated: November 25, 2016.

Renee Murphy,

Designated Federal Officer for the CIPAC.

[FR Doc. 2016–29339 Filed 12–6–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5946–N–03]

Notice of Regulatory Waiver Requests Granted for the Third Quarter of Calendar Year 2016

AGENCY: Office of the General Counsel, HUD.

ACTION: Notice.

SUMMARY: Section 106 of the Department of Housing and Urban Development Reform Act of 1989 (the HUD Reform Act) requires HUD to publish quarterly **Federal Register** notices of all regulatory waivers that HUD has approved. Each notice covers the quarterly period since the previous **Federal Register** notice. The purpose of this notice is to comply with the requirements of section 106 of the HUD Reform Act. This notice contains a list of regulatory waivers granted by HUD during the period beginning on July 1, 2016, and ending on September 30, 2016.

FOR FURTHER INFORMATION CONTACT: For general information about this notice, contact Ariel Pereira, Associate General Counsel for Legislation and Regulations, Department of Housing and Urban Development, 451 7th Street SW., Room 10282, Washington, DC 20410–0500, telephone 202–708–3055 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

For information concerning a particular waiver that was granted and for which public notice is provided in this document, contact the person whose name and address follow the description of the waiver granted in the accompanying list of waivers that have been granted in the third quarter of calendar year 2016.

SUPPLEMENTARY INFORMATION:

Section 106 of the HUD Reform Act added a new section 7(q) to the Department of Housing and Urban Development Act (42 U.S.C. 3535(q)), which provides that:

1. Any waiver of a regulation must be in writing and must specify the grounds for approving the waiver;

2. Authority to approve a waiver of a regulation may be delegated by the Secretary only to an individual of Assistant Secretary or equivalent rank, and the person to whom authority to waive is delegated must also have authority to issue the particular regulation to be waived;

3. Not less than quarterly, the Secretary must notify the public of all waivers of regulations that HUD has approved, by publishing a notice in the **Federal Register**. These notices (each covering the period since the most recent previous notification) shall:

a. Identify the project, activity, or undertaking involved;

b. Describe the nature of the provision waived and the designation of the provision;

c. Indicate the name and title of the person who granted the waiver request;

d. Describe briefly the grounds for approval of the request; and

e. State how additional information about a particular waiver may be obtained.

Section 106 of the HUD Reform Act also contains requirements applicable to waivers of HUD handbook provisions that are not relevant to the purpose of this notice.

This notice follows procedures provided in HUD's Statement of Policy on Waiver of Regulations and Directives issued on April 22, 1991 (56 FR 16337). In accordance with those procedures and with the requirements of section 106 of the HUD Reform Act, waivers of regulations are granted by the Assistant Secretary with jurisdiction over the regulations for which a waiver was requested. In those cases in which a General Deputy Assistant Secretary granted the waiver, the General Deputy Assistant Secretary was serving in the absence of the Assistant Secretary in accordance with the office's Order of Succession.

This notice covers waivers of regulations granted by HUD from July 1, 2016 through September 30, 2016. For ease of reference, the waivers granted by HUD are listed by HUD program office (for example, the Office of Community Planning and Development, the Office of Fair Housing and Equal Opportunity, the Office of Housing, and the Office of Public and Indian Housing, etc.). Within each program office grouping, the waivers are listed sequentially by the regulatory section of title 24 of the Code of Federal Regulations (CFR) that is being waived. For example, a waiver of a provision in 24 CFR part 58 would be listed before a waiver of a provision in 24 CFR part 570.

Where more than one regulatory provision is involved in the grant of a particular waiver request, the action is listed under the section number of the first regulatory requirement that appears in 24 CFR and that is being waived. For example, a waiver of both § 58.73 and § 58.74 would appear sequentially in the listing under § 58.73.

Waiver of regulations that involve the same initial regulatory citation are in time sequence beginning with the earliest-dated regulatory waiver.

Should HUD receive additional information about waivers granted during the period covered by this report (the third quarter of calendar year 2016) before the next report is published (the fourth quarter of calendar year 2016), HUD will include any additional waivers granted for the third quarter in the next report.

Accordingly, information about approved waiver requests pertaining to HUD regulations is provided in the Appendix that follows this notice.

Dated: December 1, 2016.

Tonya T. Robinson,

Acting General Counsel.

Appendix

Listing of Waivers of Regulatory Requirements Granted by Offices of the Department of Housing and Urban Development July 1, 2016 Through September 30, 2016

Note to Reader: More information about the granting of these waivers, including a copy of the waiver request and approval, may be obtained by contacting the person whose name is listed as the contact person directly after each set of regulatory waivers granted.

The regulatory waivers granted appear in the following order:

I. Regulatory Waivers Granted by the Office of Community Planning and Development
II. Regulatory Waivers Granted by the Office of Fair Housing and Equal Opportunity
III. Regulatory Waivers Granted by the Office of Housing
IV. Regulatory Waivers Granted by the Office of Public and Indian Housing

I. Regulatory Waivers Granted by the Office of Community Planning and Development

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 58.22(a).

Project/Activity: The Lombardi Project is a residential and retail mixed-use project at

371 North Avenue in New Rochelle, New York.

Nature of Requirement: Funds may not be spent prior to the completion of the environmental review process to avoid choice-limiting actions. The regulation allows for a waiver of that requirement if the grantee can demonstrate good cause and no harm.

Granted By: Harriet Tregoning, Principal Deputy Assistant Secretary for Community Planning & Development.

Date Granted: July 6, 2016.

Reason Waived: The grantee met the regulatory requirements for the waiver and demonstrated good cause for its granting.

Contact: James M. Potter, Environmental Planning Division, Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7212, Washington, DC 20410, telephone (202) 402 4610.

• *Regulation:* 24 CFR 58.22.

Project/Activity: Former Phenix Elementary School, City of West Des Moines, Iowa.

Nature of Requirement: The regulation provides that ''Neither a recipient nor any participant in the development process, including public or private nonprofit or for-profit entities, or any of their contractors, may commit HUD assistance under [the State CDBG–DR grant program] on an activity or project until HUD or the state has approved the recipient's Request for Release of Funds (RROF) and the related certification from the responsible entity. In addition, until the RROF and the related certification have been approved, neither a recipient nor any participant in the development process may commit non-HUD funds on or undertake an activity or project under [the State CDBG–DR grant program] if the activity or project would have an adverse environmental impact or limit the choice of reasonable alternatives.'' In this situation, the City, as grant recipient, committed non-HUD funds to acquire real property, the former Phenix Elementary school property, subsequent to the award of a State CDBG–DR grant but prior to the City receiving an approved Request for Release of Funds and Certification (RROF) from the State.

Granted By: Harriet Tregoning, Principal Deputy Assistant Secretary for Community Planning & Development.

Date Granted: August 9, 2016.

Reason Waived: The violation is regulatory in nature, not statutory. Implementation of the proposed project is consistent with HUD's mission and will advance HUD program goals related to community development, economic development and support of the city's affordable housing supply. The project will benefit the community by preserving a historic landmark, the Phenix Elementary School. The City has agreed to change its processes and procedures and to build its internal capacity to ensure future violations do not occur. Granting a waiver should not result in an unmitigated adverse environmental impact provided the City implements the conditions associated with the waiver approval.

Contact: Paul F. Mohr, Regional Environmental Officer, Community Planning and Development, Department of Housing and Urban Development, 400 State Avenue, Room 200, Kansas City, KS 66101, telephone (913) 551 5818.

• *Regulation:* 24 CFR 92.500(d)(1)(C)—HOME Expenditure Requirement.

Project/Activity: The Commonwealth of Puerto Rico requested a waiver of 24 CFR 92.500(d)(1)(C), which requires that a participating jurisdiction expend its annual allocation of HOME funds within five years after HUD notifies the participating jurisdiction that HUD has executed the jurisdiction's HOME Investment Partnership Agreement. The Commonwealth requested this waiver to provide it additional time to expend $380,798 of HOME funds.

Nature of Requirement: The regulation at 24 CFR 92.500(d)(1)(C) requires HUD to reduce or recapture any HOME funds in a participating jurisdiction's HOME Investment Trust Fund that are not expended within five years of HUD's notification to the participating jurisdiction that HUD has executed the HOME grant agreement. The Commonwealth failed to disburse $380,798 of HOME funds by its expenditure deadline of July 31, 2016.

Granted By: Harriet Tregoning, Principal Deputy Assistant Secretary for Community Planning & Development.

Date Granted: August 22, 2016.

Reason Waived: The Commonwealth repaid $5,126,234.53 to its local HOME account with non-federal funds to resolve HUD OIG audit findings that it expended HOME funds for ineligible purposes. While the Commonwealth made significant progress by disbursing over $25 million in HOME funds between August 1, 2015 and July 31, 2016, the size and timing of the repayments did not afford it sufficient time to identify new projects for the entire amount of repaid funds. HUD granted the waiver to permit the Commonwealth additional time to expend funds on new affordable housing projects for low-income residents.

Contact: Virginia Sardone, Director, Office of Affordable Housing Programs, Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7164, Washington, DC 20410, telephone (202) 708–2684.

• *Regulation:* 24 CFR 91.15(a)(2)—Consolidated Plan Requirements.

Project/Activity: American Samoa, the Commonwealth of Puerto Rico, and the states of Arkansas, California, New Hampshire, and Texas requested a waiver of 24 CFR 91.15(a)(2) of the regulation, which requires each grantee to submit its Housing Trust Fund (HTF) allocation plan to HUD no later than August 16, 2016. The grantees requested this waiver to provide additional time to develop their HTF allocation plans and conduct the required citizen participation process.

Nature of Requirement: As a condition of receiving funding, each HTF grantee is required to submit an HTF allocation plan to HUD, the requirements of which are incorporated into the consolidated plan regulations under 24 CFR part 91. The provisions at 24 CFR 91.15(a)(2) require that each grantee submit its HTF allocation plan to HUD no later than August 16, 2016.

Granted By: Harriet Tregoning, Principal Deputy Assistant Secretary for Community Planning & Development.

Date Granted: September 6, 2016.

Reason Waived: FY 2016 is the first year in which funding is being made available for the HTF program. HUD published *CPD Notice 16–07* Guidance for HTF Grantees on Fiscal Year 2016 Housing Trust Fund (HTF) Allocation Plans on April 28, 2016, and the HTF allocation amounts in the **Federal Register** on May 5, 2016. Because some grantees did not have sufficient time to develop their HTF allocation plans and conduct the required citizen participation process, HUD waived the August 16, 2016 deadline and extended the deadline for submission of 2016 HTF allocation plans as follows:

Grantee Name	New Deadline
American Samoa	August 31, 2016.
Commonwealth of Puerto Rico	November 14, 2016.
State of Arkansas	September 30, 2016.
State of California	September 30, 2016.
State of New Hampshire	September 14, 2016.
State of Texas	October 17, 2016.

Contact: Virginia Sardone, Director, Office of Affordable Housing Programs, Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7164, Washington, DC 20410, telephone (202) 708–2684.

II. Regulatory Waivers Granted by Office of Fair Housing and Equal Opportunity

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 115.305(a).

Project/Activity: Fair Housing Assistance Program (FHAP); 2016 Enforcement Fund.

Nature of Requirement: 24 CFR 115.305(a) allows grants of Special Enforcement Efforts (SEE) funds to participants in the Fair Housing Assistance Program, but limits the award to 20 percent of the participant's total FHAP cooperative agreement for the previous contract year.

Granted By: Assistant Secretary Gustavo Velazquez.

Date Granted: April 29, 2016.

Reason Waived: The waiver allows FHEO to provide certain FHAP agencies with SEE funds above the amount set forth in the regulation in order to support ongoing, protracted, or complex litigation associated with the enforcement of their substantially equivalent fair housing laws.

Contact: Joseph A. Pelletier, Director, Fair Housing Assistance Program, Fair Housing Equal Opportunity, Department of Housing and Urban Development, 451 7th Street SW., Room 5206, Washington, DC, 20410, telephone (202) 402–2126.

III. Regulatory Waivers Granted by the Office of Housing—Federal Housing Administration (FHA)

For further information about the following regulatory waivers, please see the name of

the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 200.73(c).

Project/Activity: R.H. Floyd Memorial Apartments, FHA Project Number 061–1352, Summerville, Georgia. The City of Summerville, GA received a Commitment to Enter into Housing Assistance Payments Contract (CHAP) to convert its entire public housing unit inventory to project based Section 8 rental housing. The lender, Bellwether Enterprise is seeking FHA financing to renovate the 223 units.

Nature of Requirement: The 24 CFR part 200.73(c) which, states that a site must contain no less than 5 rental dwelling units. Section 3.1.CC of the MAP Guide permits a project with two or noncontiguous parcels of land when the parcels comprise one marketable, manageable real estate entity.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: July 5, 2016.

Reason Waived: The waiver was granted to allow the City of Summerville, GA to convert its entire public housing unit inventory to project based Section 8 rental housing. Six of the parcels have less than the minimum of five required units. Since the remaining 17 parcels are in compliance, the intent of 24CFR 200.73(c) is essentially fulfilled.

Contact: Daniel J. Sullivan, Acting Director, Office of Multifamily Production, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6134, Washington, DC 20410, telephone (202) 402–6130.

• *Regulation:* 24 CFR 200.73(c).

Project/Activity: The Heritage Village Apartments, FHA Project Number 042–35702, Toledo, Ohio. The subject property was initially developed and insured under Section 221(d)(4) of the National Housing Act under the project name of Vistula Heritage Village. The property has a project-based Section 8 HAP contract that covers all 250 units and consists of 21 separate parcels of which all but seven have more than five units per site.

Nature of Requirement: The 24 CFR part 200.73(c) which, states that a site must contain no less than 5 rental dwelling units. Section 3.1.O.l.CC of the MAP Guide permits a project with two or more contiguous parcels of land when the parcels comprise one marketable, manageable real estate entity.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: July 22, 2016.

Reason Waived: The waiver was granted to allow much needed preservation in an historic section of Toledo. The property has been managed as one project since inception; therefore, the intent of 24 CFR 200.73(c) is essentially fulfilled. The waiver allows Heritage Village Apartments to preserve and maintain affordable rental housing for low income families

Contact: Daniel J. Sullivan, Acting Director, Office of Multifamily Production, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6134, Washington, DC 20410, telephone (202) 402–6130.

• *Regulation:* 24 CFR 219.220(b).

Project/Activity: Golden Spike Apartments, FHA Project Number 101–44026, Denver, Colorado. Colorado Veteran and Retired Railroaders, Incorporated (Owner) seeks approval to defer repayment of the Flexible Subsidy Operating Assistance Loan on the subject project.

Nature of Requirement: The regulation at 24 CFR 219.220(b) (1995), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Properties, states ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project.''

Granted by: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: July 7, 2016.

Reason Waived: The owner requested and was granted a waiver of the requirement to repay the Flexible Subsidy Operating Assistance Loan in full when it became due. Deferring the loan payment will preserve this affordable housing resource for an additional 20 years through the execution and recordation of a Rental Use Agreement.

Contact: Marilyn Carlson, Senior Account Executive, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6156, Washington, DC 20410, telephone (202) 402–4744.

• *Regulation:* 24 CFR 219.220(b).

Project/Activity: Cumberland Court Apartments, FHA Project Number 075–44039T, Oshkosh, Wisconsin. Cumberland Court Housing Commission, Incorporated (Owner) seeks approval to defer repayment of the Flexible Subsidy Operating Assistance Loan on the subject project.

Nature of Requirement: The regulation at 24 CFR 219.220(b) (1995), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Properties, states ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project.''

Granted by: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: July 26, 2016.

Reason Waived: The owner requested and was granted a waiver of the requirement to repay the Flexible Subsidy Operating Assistance Loan in full when it became due. Deferring the loan payment will preserve this affordable housing resource for an additional 20 years through the execution and recordation of a Rental Use Agreement.

Contact: Valencia Hare, Senior Account Executive, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6180, Washington, DC 20410, telephone (202) 402–6103.

• *Regulation:* 24 CFR 219.220(b)

Project/Activity: Golden Spike Apartments, FHA Project Number 101–44026, Denver, Colorado. Colorado Veteran and Retired Railroaders, Incorporated (Owner) seeks approval to defer repayment of the Flexible Subsidy Operating Assistance Loan on the subject project.

Nature of Requirement: The regulation at 24 CFR 219.220(b) (1995), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Properties, states ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project.''

Granted by: Edward L. Golding, Principal Deputy Assistant Secretary for Housing, H

Date Granted: July 7, 2016

Reason Waived: The owner requested and was granted a waiver of the requirement to repay the Flexible Subsidy Operating Assistance Loan in full when it became due. Deferring the loan payment will preserve this affordable housing resource for an additional 20 years through the execution and recordation of a Rental Use Agreement.

Contact: Marilyn Carlson, Senior Account Executive, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410–8000, telephone: (202) 402–4744.

• *Regulation:* 24 CFR 219.220(b).

Project/Activity: Manchester Knolls Cooperative and Manchester Knolls II Cooperative, FHA Project Numbers 071–44073 and 071–44075, North Chicago, Illinois. Manchester Knolls Cooperative, Incorporated (owner) seeks approval to defer repayment of the Flexible Subsidy Operating Assistance Loans on the subject projects.

Nature of Requirement: The regulation at 24 CFR 219.220(b) (1995), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Properties, states ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project.''

Granted by: Edward L. Golding, Principal Deputy Assistant Secretary for Housing, H.

Date Granted: September 14, 2016.

Reason Waived: The owner requested and was granted a waiver of the requirement to repay the Flexible Subsidy Operating Assistance Loans in full when they became due. Deferring the loan payments will preserve these affordable housing resources for an additional 35 years through the execution and recordation of a Rental Use Agreement.

Contact: Crystal Martinez, Senior Account Executive, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6174, Washington, DC 20410, telephone (202) 402–3718.

• *Regulation:* 24 CFR 232.7.

Project/Activity: CountryHouse of Grand Island is a memory care facility. The facility does not meet the requirements of 24 CFR 232.7 ''Bathroom'' of FHA's regulations. The project is located in Grand Island, NE.

Nature of Requirement: The regulation at 24 CFR 232.7 mandates in a board and care home or assisted living facility that not less than one full bathroom must be provided for every four residents. Also, the bathroom cannot be accessed from a public corridor or area.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: August 25, 2016.

Reason Waived: The project is for memory care, all rooms have half-bathrooms and the ratio of residents to full bathroom rooms is 6.75/1. The memory care residents need assistance with bathing. The project meets the State of Nebraska's licensing requirements for bathing and toileting facilities.

Contact: Vance T. Morris, Operations Manager, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 2337, Washington, DC 20401, telephone (202) 402–2419.

• *Regulation:* 24 CFR 232.7.

Project/Activity: Devonshire Retirement Village is a memory care facility. The facility does not meet the requirements of 24 CFR 232.7 ''Bathroom'' of FHA's regulations. The project is located in Lapeer, MI.

Nature of Requirement: The regulation at 24 CFR 232.7 mandates in a board and care home or assisted living facility that not less than one full bathroom must be provided for every four residents. Also, the bathroom cannot be accessed from a public corridor or area.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: September 21, 2016.

Reason Waived: The project is for memory care, all rooms have half-bathrooms and the ratio of residents to full bathroom rooms is 7:1. The memory care residents need assistance with bathing. The project meets the State of Michigan's licensing requirements for bathing and toileting facilities.

Contact: Vance T. Morris, Operations Manager, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 2337, Washington, DC 20401, telephone (202) 402–2419.

• *Regulation:* 24 CFR 232.7.

Project/Activity: White Pines of Fridley is a memory care facility. The facility does not meet the requirements of 24 CFR 232.7 ''Bathroom'' of FHA's regulations. The project is located in Fridley, MN.

Nature of Requirement: The regulation at 24 CFR 232.7 mandates in a board and care home or assisted living facility that not less than one full bathroom must be provided for every four residents. Also, the bathroom cannot be accessed from a public corridor or area.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: September 27, 2016.

Reason Waived: The project is for memory care, all rooms have half-bathrooms and the ratio of residents to full bathroom rooms is 7:1. The memory care residents need assistance with bathing. The project meets the State of Minnesota's licensing requirements for bathing and toileting facilities.

Contact: Vance T. Morris, Operations Manager, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 2337, Washington, DC 20401, telephone (202) 402–2419.

• *Regulation:* 24 CFR 232.1005.

Project/Activity: Stygler Commons and Portage Trail Village are two existing Section 202 projects that received Assisted Living Conversion Program grants to convert the projects to assisted living facilities. All operating licenses and accounts receivable associated with revenue generated as a result of the care provided at these two projects were pledged as collateral for a bond issuances used the finance the projects. The projects are located in Gahanna and Cuyahoga Falls, Ohio.

Nature of Requirement: The regulation at 24 CFR 232.1005 mandates that all accounts deriving from the operation of the property, including operator accounts and including all funds received from any source or derived from the operation of the facility, are project assets subject to control under the insured mortgage loan's transactional documents, including, without limitation, the operator's regulatory agreement.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: September 21, 2016.

Reason Waived: The waiver of the requirement, in part, is required to allow the projects to refinance. The bond trustee agreed to release the licenses associated with the projects from the collateral securing the bond obligation. However, all accounts receivable associated with the revenue generated as a result of the care provided continue to secure the bond obligation. All other accounts will be pledged in accordance with the Department's requirements. The service provider for the two projects agreed to provide a corporate guarantee to guarantee both loans.

Contact: Vance T. Morris, Operations Manager, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 2337, Washington, DC 20401, telephone (202) 402–2419.

• *Regulation:* 24 CFR 242.21.

Project/Activity: LRGHealthcare (LRG) is a not-for-profit 501(c)(3) organization that operates two facilities in New Hampshire: Lakes Region General Hospital, a 137-bed Sole Community Hospital in Laconia, NH, and Franklin Regional Hospital, a 25-bed acute care critical access hospital that has a 10-bed psychiatric receiving facility, in Franklin, NH.

Nature of Requirement: The regulation mandates that application fees accompanying Section 242 applications cannot be refunded, in whole or in part.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: August 3, 2016.

Reason Waived: KeyBanc Capital Markets, Inc., on behalf of LRG, submitted an application (and an application fee in the amount of $204,635.50) for a Section 223(f) loan in May 2015. After a brief review of the application, the Office of Hospital Facilities (OHF) determined that the application could not be approved. Instead, the Lender submitted a request for an interest rate reduction, which reduced the interest rate from 6.38% to 3.7%. This financing closed in September 2015. Typically application fees are collected to offset the resources expended to process an application, but HUD expended no resources in evaluating LRG's application. The refund will help improve LRG's cash position.

Contact: Shelley M. McCracken-Rania, Senior Financial Analyst, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 2247, Washington, DC 20410, telephone (202) 402–5366.

• *Regulation:* 24 CFR 266.200(c)(2).

Project/Activity: Federal Financing Bank (FFB) Risk Sharing Initiative, Equity Take-Out, Rhode Island Housing Mortgage Corporation (Rhode Island Housing).

Nature of Requirement: 24 CFR 266.200(c)(2) HUD's regulation at 24 CFR 266.200(c)(2) allows existing projects to be refinanced if certain criteria are met. If the property is subject to an HFA financed loan to be refinanced and such refinancing will result in the preservation of affordable housing, refinancing of these properties is permissible if project occupancy is not less than 93 percent (to include consideration of rent in arrears), based on the average occupancy in the project over the most recent 12 months, and the mortgage does not exceed an amount supportable by the lower of the unit rents being collected under the rental assistance agreement or the unit rents being collected at unassisted projects in the market area that are similar in amenities and location to the project for which insurance is being requested. The HUD-insured mortgage may not exceed the sum of the existing indebtedness, cost of refinancing, the cost of repairs and reasonable transaction costs as determined by the Commissioner. If a loan to be refinanced has been in default within the 12 months prior to application for refinancing, the HFA must assume not less than 50 percent of the risk.

Equity take-outs for existing projects (refinance transactions): Permit the insured mortgage to exceed the sum of the total cost of acquisition, cost of financing, cost of repairs, and reasonable transaction costs or ''equity take-outs'' in refinances of HFA-financed projects and those outside of HFA's portfolio if the result is preservation with the following conditions:

1. Occupancy is no less than 93% for previous 12 months;

2. No defaults in the last 12 months of the HFA loan to be refinanced;

3. A 20-year affordable housing deed restriction placed on title that conforms to the 542(c) statutory definition;

4. A Property Capital Needs Assessment (PCNA) must be performed and funds escrowed for all necessary repairs, and reserves funded for future capital needs; and

5. For projects subsidized by Section 8 Housing Assistance Payment (HAP) contracts: Owner agrees to renew HAP contract(s) for 20-year term, (subject to appropriations and statutory authorization, etc.,), and existing and post-refinance HAP residual receipts are set aside to be used to reduce future HAP payments.

Granted by: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: September 6, 2016.

Reason Waived: Necessary to effectuate the Federal Financing Bank (FFB) Risk Sharing

Initiative between Housing and Urban Development and the Treasury Department/FFB announced in Fiscal Year 2014. The waivers are consistent with changes Multifamily is seeking now to the regulation and as previously approved in March 2015 for the first 11 HFAs participating in the Initiative. Under this Initiative, FFB provides capital to participating Housing Finance Agencies (HFAs) to make multifamily loans insured under the FHA Multifamily Risk Sharing Program.

Contact: Daniel J. Sullivan, Acting Director, Office of Multifamily Production, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6134, Washington, DC, 20410, telephone (202) 402–6130.

• *Regulation:* 24 CFR 290.30(a).

Project/Activity: Eastern Parkway Apartments, FHA Project Number 012–57049 V and W, Brooklyn, New York. Eastern Parkway HAP Associates, L.P. (Owner) seeks approval to waive the non-competitive sale of two HUD-held multifamily mortgages.

Nature of Requirement: The regulation at 24 CFR 290.30(a), which governs the sale of HUD-held mortgages, states that ''[e]xcept as otherwise provided in Section 290.31(a)(2), HUD will sell HUD-held multifamily mortgages on a competitive basis.''

Granted by: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: September 14, 2016.

Reason Waived: The owner requested and was granted a waiver of the non-competitive sale of two HUD-held multifamily mortgages. A waiver allows the Department to assign the mortgages to the owner's new mortgagee to avoid paying mortgage recording tax in the State of New York.

Contact: Susanna Oyewole, Account Executive, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6168, Washington, DC 20410, telephone (202) 402–6080.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Victoria at COMM22, San Diego, CA, Project Number: 129–EE036/CA33–S101–001.

Nature of Requirement: Section 891.165 provides that the duration of the fund reservation of the capital advance is 18-months from the date of issuance with limited exceptions up to 36 months, as approved by HUD on a case-by-case basis.

Granted By: Edward L. Golding, Principal Deputy Assistant Secretary for Housing.

Date Granted: September 13, 2016.

Reason Waived: Additional time was needed to meet other requirements of the State of California and time for the tax credit investor to review and approve the loan documents.

Contact: Alicia Anderson, Branch Chief, Grants and New Funding, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6138, Washington, DC 20410, telephone (202) 402–5787.

IV. Regulatory Waivers Granted by the Office of Public and Indian Housing

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 5.801(c)(1) and 24 CFR 5.801(d)(1).

Project/Activity: Brown County North East Kansas Community Action Program (KS168).

Nature of Requirement: The regulation establishes certain reporting compliance dates. The audited financial statements are required to be submitted to the Real Estate Assessment Center (REAC) no later than nine months after the housing authority's (HA) fiscal year end (FYE), in accordance with the Single Audit Act and OMB Circular A–133.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 21, 2016.

Reason Waived: Brown County North Kansas Community Action Program, NEK–CAP (HA), a Section 8 only entity, requested an extension to submit its audited financial data for the fiscal year end (FYE) of September 30, 2015, to align with its Housing Choice Voucher (HCV) program. The HCV program fiscal year end change was granted on December 4, 2015. The additional time would permit the auditor necessary time to compile and complete NEK–CAP's required audited financial data submission to the Department.

This FASS audited financial submission waiver (extension) does not apply to Single Audit submissions to the Federal Audit Clearinghouse; the HA is required to meet the Single Audit due date.

Contact: Dee Ann R. Walker, Acting Program Manager, NASS, Real Estate Assessment Center, Office of Public and Indian Housing, Department of Housing and Urban Development, 550 12th Street SW., Suite 100, Washington, DC 20410, telephone (202) 475–7908.

• *Regulation:* 24 CFR 902.25.

Project/Activity: Rayville Housing Authority (LA105).

Nature of Requirement: Physical inspections are required to ensure that public housing units are decent, safe, sanitary and in good repair, as determined by an inspection conducted in accordance with HUD's Uniform Physical Condition Standards (UPCS). Baseline inspections will have all properties inspected regardless of previous PHAS designation or physical inspection scores.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Partially Granted: July 11, 2016.

Reason Waived: Rayville Housing Authority (HA), requested to be waived from all physical inspections and physical condition scoring of property/units for its fiscal year end (FYE) of September 30, 2016.

Pursuant to 24 CFR 5.110, the HA was granted a partial waiver for good cause of the PHAS and physical inspection score for its FYE September 30, 2016. The HA was advised that the inspection results will be for informational purposes and would not serve as the inspection of record. The HA was also advised that September 30, 2017, would be the baseline year to determine its eligibility for Small PHA Deregulation and that a new inspection would be required upon that date.

Contact: Dee Ann R. Walker, Acting Program Manager, NASS, Real Estate Assessment Center, Office of Public and Indian Housing, Department of Housing and Urban Development, 550 12th Street SW., Suite 100, Washington, DC 20410, telephone (202) 475–7908.

• *Regulation:* 24 CFR 902.25.

Project/Activity: Bogalusa Housing Authority (LA024).

Nature of Requirement: Physical inspections are required to ensure that public housing units are decent, safe, sanitary and in good repair, as determined by an inspection conducted in accordance with HUD's Uniform Physical Condition Standards (UPCS). Baseline inspections will have all properties inspected regardless of previous PHAS designation or physical inspection scores.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Partially Granted: August 9, 2016.

Reason Waived: Bogalusa Housing Authority (HA), requested to be waived from all physical inspections and physical condition scoring of property/units for its fiscal year end (FYE) of September 30, 2016.

Pursuant to 24 CFR 5.110, the HA was granted a partial waiver for good cause of the PHAS and physical inspection score for its FYE September 30, 2016. The HA was advised that the inspection results will be for informational purposes and would not serve as the inspection of record. The HA was also advised that September 30, 2017, would be the baseline year to determine its eligibility for Small PHA Deregulation and that a new inspection would be required upon that date.

Contact: Dee Ann R. Walker, Acting Program Manager, NASS, Real Estate Assessment Center, Office of Public and Indian Housing, Department of Housing and Urban Development, 550 12th Street SW., Suite 100, Washington, DC 20410, telephone (202) 475–7908.

• *Regulation:* 24 CFR 982.251(c).

Project/Activity: Department of Housing and Community Development in Boston, Massachusetts requested a waiver of 24 CFR 982.251(c) so that HUD-Veterans Affairs Supportive Housing (VASH) families do not have to be placed on the agency's waiting list for HUD–VASH project-based voucher (PBV) assistance.

Nature of Requirement: 24 CFR 982.251(c) states that a PHA shall select families to receive PBV assistance from its waiting list.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 29, 2016.

Reason Waived: This regulation was waived so that the VA could refer families to a new veterans' facility in Bedford, Massachusetts without placing their names on a waiting list. Having to use a waiting list for PBV assistance could delay housing these veterans. In addition, HUD–VASH families are not placed on a waiting list for tenant-based voucher assistance.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW.,

Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.251(c).

Project/Activity: Brockton Housing Authority in Brockton, Massachusetts, requested a waiver of 24 CFR 982.251(c) so that HUD-Veterans Affairs Supportive Housing (VASH) families do not have to be placed on the agency's waiting list for HUD–VASH project-based voucher (PBV) assistance.

Nature of Requirement: 24 CFR 982.251(c) states that a PHA shall select families to receive PBV assistance from its waiting list.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 19, 2016.

Reason Waived: This regulation was waived so that the VA could refer families to a new veterans' facility on the grounds of the Brockton VA Medical Center in Brockton, Massachusetts without placing their names on a waiting list. Having to use a waiting list for PBV assistance could delay housing these veterans. In addition, HUD–VASH families are not placed on a waiting list for tenant-based voucher assistance.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.503(c).

Project/Activity: Howard County Housing Commission (HCHC) in Columbia, Maryland, requested a waiver of 24 CFR 982.503(c) so that it could receive approval for exception payment standards at 135 percent of the fair market rents.

Nature of Requirement: This regulation requires certain conditions prior to the approval of area-wide exception payment standards which the HCHC did not meet.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: August 19, 2016.

Reason Waived: This waiver was granted because in 2016 the separate FMRs for Columbia were eliminated and combined with the FMRs for the Baltimore Metropolitan Statistical Area which will result in an increase in family rents after the tenant protection is eliminated.

Contact: Becky Primeaux, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulations:* 24 CFR 982.503(c)(4)(ii), 982.503(c)(5) and 982.503(c)(3)(i)(B).

Project/Activity: Housing Authority of the City of Lake Charles in Lake Charles, Louisiana, requested a waiver of these regulations so that it could receive approval for exception payment standards at 135 percent of the fair market rents (FMR).

Nature of Requirement: These regulations require: (1) A six-month wait until payment standards could go above the basic range; (2) exception payment standards could not include more than 50 percent of the FMR area; and (3) approval must be supported by statistically representative rental housing survey data.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 19, 2016.

Reason Waived: These waivers were granted because of a shock to the rental housing market caused by increased economic activity in the FMR area due to the expansion of the petrochemical industry. These corporations leased hundreds of units that were previously available for voucher participants.

Contact: Becky Primeaux, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.503(e)(1).

Project/Activity: Housing Works in Redmond, Oregon, requested a waiver of 24 CFR 982.505(e)(1) to enable the housing authority to adopt success rate payment standards.

Nature of Requirement: 24 CFR 982.505(e)(1) states that a public housing agency (PHA) may obtain HUD Field Office approval of success rate payment standard amounts provided the PHA demonstrates that is has established payment standard amounts for all unit sizes in the entire PHA's jurisdiction with the fair market rent (FMR) area at 110 percent of the published FMR for at least the six-month period prior to the time the request for success rate payment standards is made to HUD.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: August 9, 2016.

Reason Waived: One of the counties in the FMR area did not warrant success rate payment standards as the non-success rate payment standards were adequate in that county.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(c)(4).

Project/Activity: Vallejo Housing Authority in Vallejo, California, requested a waiver of 24 CFR 982.505(c)(4) so that it could approve an exception payment standard amount above 120 percent of the fair market rents (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(c)(4) states that if the payment standard amount is increased during the term of the housing assistance payment contract, the increased payment standard shall be used to calculate the monthly housing assistance payment for the family beginning at the effective date of the family's first regular reexamination on or after the effect date of the increase in the payment standard amount.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 25, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share subsequent to the owner's rent increase prior to the annual recertification.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: San Francisco Housing Authority in San Francisco, California, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rents (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 9, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: San Francisco Housing Authority in San Francisco, California, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rents (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 9, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40

percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Housing Authority of the County of Los Angeles in Alhambra, California, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rents (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 20, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202)708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Housing Authority of Douglas County in Roseburg, Oregon, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rents (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 21, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Bellingham Whatcom County Housing Authorities in Bellingham, Washington, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rents (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 25, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Vallejo Housing Authority in Vallejo, California, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rent (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: August 9, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Arvada Housing Authority in Arvada, California, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rent (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: August 19, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Ithaca Housing Authority in Ithaca, New York, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rent (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 19, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 982.505(d).

Project/Activity: Boston Housing Authority in Boston, Massachusetts, requested a waiver of 24 CFR 982.505(d) so that it could approve an exception payment standard amount above 120 percent of the fair market rent (FMR) as a reasonable accommodation.

Nature of Requirement: 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is no more than 120 percent of the FMR for the unit size.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 30, 2016.

Reason Waived: This regulation was waived as a reasonable accommodation to allow a disabled participant to receive housing assistance and pay no more than 40 percent of its adjusted income toward the family share.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and

Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 985.101(a).

Project/Activity: The Flint Housing Commission (FHC) in Flint, Michigan, requested a waiver of 24 CFR 985.101(a) so that it could submit its Section Eight Management Assessment Program (SEMAP) certification after the deadline.

Nature of Requirement: 24 CFR 985.101(a) states a PHA must submit the HUD-required SEMAP certification form within 60 calendar days after the end of its fiscal year.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 19, 2016.

Reason Waived: This waiver was granted for the FHC's fiscal year ending August 29, 2016. The waiver was approved because of circumstances beyond the PHA's control and to prevent additional administrative burdens for the PHA and field office.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 985.101(a).

Project/Activity: Tallahassee Housing Authority (THA) in Tallahassee, Florida, requested a waiver of 24 CFR 985.101(a) so that it could submit its Section Eight Management Assessment Program (SEMAP) certification after the deadline.

Nature of Requirement: 24 CFR 985.101(a) states a PHA must submit the HUD-required SEMAP certification form within 60 calendar days after the end of its fiscal year.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 28, 2016.

Reason Waived: This waiver was granted for the THA's fiscal year ending August 29, 2016. The waiver was approved because of circumstances beyond the THA's control and to prevent additional administrative burdens for the PHA and field office.

Contact: Becky Primeaux, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• *Regulation:* 24 CFR 1000.224.

Project/Activity: Quechan Housing Authority, Winterhaven, CA 92283.

Nature of Requirement: HUD has the general authority under Section 101(b)(2) of NAHASDA to waive any IHP requirement when an Indian Tribe cannot comply with IHP requirements due to exigent circumstances beyond its control, for a period of not more than 90 days.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: July 14, 2016.

Reason Waived: A waiver was requested and granted to extend the due date for Quechan Housing Authority's 2017 Indian Housing Plan because of exigent circumstances in order to provide flexibility to address the needs of the Indian Tribe.

Contact: Deborah Apsey, GM Specialist, Office of Public and Indian Housing, Department of Housing and Urban Development, 1 North Central Avenue, Suite 600, Phoenix, Arizona 85004, telephone (602) 379–7217.

• *Regulation:* 24 CFR 1006.410(a)(2).

Project/Activity: Native Hawaiian Housing Block Grant Program Annual Performance Report (APR) Honolulu, Hawaii.

Nature of Requirement: Each fiscal year the Department of Hawaiian Home Lands (DHHL) must submit a performance report to HUD within 60 days of the end of DHHL's fiscal year.

Granted By: Lourdes Castro Ramírez, Principal Deputy Assistant Secretary for Public and Indian Housing.

Date Granted: September 19, 2016.

Reason Waived: DHHL was granted a 30-day extension to the due date to complete the subrecipient monitoring and allow public comment on the APR.

Contact: Claudine Allen, Program Specialist, Office of Public and Indian Housing, Department of Housing and Urban Development, 1132 Bishop Street, Suite 1400, Honolulu, HI 96813, telephone (808) 457–4674.

[FR Doc. 2016–29354 Filed 12–6–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTM03000.L14400000.ET0000. 16X1109AF; MO# 4500095264; MTM–82330]

Public Land Order No. 7857; Extension of Public Land Order No. 7254; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order extends the duration of the withdrawal created by Public Land Order No. 7254, as corrected and amended, for an additional 20-year period, which would otherwise expire on April 9, 2017. Public Land Order No. 7254 withdrew 19,686.09 acres of public mineral estate in Toole and Liberty Counties, Montana, from location and entry under the United States mining laws, but not from leasing under the mineral leasing laws. This extension is necessary to continue to protect the Sweet Grass Hills Area of Critical Environmental Concern and surrounding areas located in Toole and Liberty Counties, Montana.

DATES: This Public Land Order is effective on April 10, 2017.

FOR FURTHER INFORMATION CONTACT: Micah Lee, Realty Specialist, at 406–262–2851, Bureau of Land Management, Havre Field Office, 3990 HWY 2 West, Havre, Montana 59501, or Deborah Sorg, Land Law Examiner at 406–896–5045, Bureau of Land Management, Montana/Dakotas State Office, 5001 Southgate Drive, Billings, Montana 59101–4669. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact either of the above individuals. The Service is available 24 hours a day, 7 days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The purpose for which the withdrawal was first made requires this extension to continue to protect the unique resources within the Sweet Grass Hills Area of Critical Environmental Concern and surrounding areas. The lands will remain open to the mineral and geothermal leasing laws and mineral materials disposal under the Materials Act.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

Public Land Order No. 7254 (62 FR 17633 (1997)), as corrected (62 FR 22964 (1997)), and amended (81 FR 796 (2016)), which withdrew 19,686.09 acres of public mineral estate in Toole and Liberty Counties, Montana from location and entry under the United States mining laws, is hereby extended for an additional 20-year period. The withdrawal extended by this order will expire on April 9, 2037, unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be further extended.

Dated: November 21, 2016.

Janice M. Schneider,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2016–29316 Filed 12–6–16; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On November 22, 2016, the Department of Justice lodged a proposed consent decree with the United States District Court for the Western District of North Carolina in the lawsuit entitled *United States* v. *CTS Corporation, Mills Gap Road Associates, and Northrop Grumman Systems Corporation,* Civil Action No. 1:16–cv–00380.

The United States, on behalf of the U.S. Environmental Protection Agency (EPA), filed this lawsuit under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The complaint seeks performance of response actions to address contamination of tricholorethylene in the groundwater at the CTS of Asheville, Inc. Superfund Site in Asheville, North Carolina.

The proposed consent decree would resolve the claims alleged in the complaint. It requires the defendants, CTS Corporation, Mills Gap Road Associates, and Northrop Grumman Corporation, to implement the remedy selected by EPA, which is estimated to cost $8,885,000.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *CTS Corporation, Mills Gap Road Associates, and Northrop Grumman Systems Corporation,* D.J. Ref. No. 90–11–2–08135/2. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

For a paper copy, please enclose a check or money order for $109.50 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $8.50.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–29355 Filed 12–6–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On December 1, 2016, the Department of Justice lodged a proposed consent decree with the United States District Court for the Western Division of North Dakota in the lawsuit entitled *United States* v. *Slawson Exploration Company, Inc.,* Civil Action No. 1:16–cv–00413–CSM.

The United States filed this lawsuit under the Clean Air Act. The United States' complaint seeks injunctive relief and civil penalties for violations of (a) the Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation and (b) North Dakota's federally-approved State Implementation Plan at well pads owned and operated by Slawson in North Dakota. The principal violations relate to alleged failures to adequately design, operate, and maintain storage tank vapor control systems, resulting in emissions of volatile organic compounds (''VOC'') and other pollutants to the atmosphere. Many of the well pads are located on the Fort Berthold Indian Reservation. The remainder are located in North Dakota outside the exterior boundaries of the reservation. The consent decree requires Slawson to perform injunctive relief and pay a $2.1 million civil penalty.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Slawson Exploration Company, Inc.,* D.J. Ref. No. 90–5–2–1–11261. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email ...	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $21.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–29276 Filed 12–6–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revisions to the confidentiality pledge for the following information collections titles.

OMB Number	Title of survey
1220–0039	Consumer Price Index Commodities and Services Survey.
1220–0008	Producer Price Index Survey.
1220–0011	Report on Employment, Payroll, and Hours.
1220–0164	National Compensation Survey.
1220–0170	Job Openings and Labor Turnover Survey (JOLTS).
1220–0189	Occupational Requirements Survey (Production).
1220–0025	International Price Program—U.S. Export Product Information.
1220–0163	Consumer Price Index Housing Survey.
1220–0042	Report on Occupational Employment.
1220–0045	Survey of Occupational Injuries.
1220–0133	Census of Fatal Occupational Injuries.
1220–0012	Employment, Wages and Contributions Report (ES–202 Program).
1220–0032	Annual Refiling Survey.
1220–0141	Cognitive and Psychological Research.
1220–0134	Multiple Worksite Report and the Report of Federal Employment and Wages.

A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the Addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the Addresses section of this notice on or before February 6, 2017.

ADDRESSES: Send comments to Nora Kincaid, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Nora Kincaid, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See Addresses section.)

SUPPLEMENTARY INFORMATION:

I. Background

Under 44 U.S.C. 3506(e), and 44 U.S.C. 3501, the Bureau of Labor Statistics is seeking comments on its revisions to the confidentiality pledges it provides to its respondents under the Confidential Information Protection and Statistical Efficiency Act (44 U.S.C. 3501) (CIPSEA). These revisions are required by the passage and implementation of provisions of the Federal Cybersecurity Enhancement Act of 2015 (H.R. 2029, Division N, Title II, Subtitle B, Sec. 223), which require the Secretary of Homeland Security to provide Federal civilian agencies' information technology systems with cybersecurity protection for their Internet traffic.

II. Current Action

Office of Management and Budget clearance is being sought for the information collections listed in the table above.

For each of these information collections, the BLS statistical confidentiality pledges will be modified to include the sentence in bold below.

Per the Federal Cybersecurity Enhancement Act of 2015, Federal information systems are protected from malicious activities through cybersecurity screening of transmitted data.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that address the revised pledge language.

Type of Review: Revision, of currently approved collections.

Agency: Bureau of Labor Statistics.

Title and OMB Numbers:

OMB Number	Title of survey
1220–0039	Consumer Price Index Commodities and Services Survey.
1220–0008	Producer Price Index Survey.
1220–0011	Report on Employment, Payroll, and Hours.
1220–0164	National Compensation Survey.
1220–0170	Job Openings and Labor Turnover Survey (JOLTS).
1220–0189	Occupational Requirements Survey (Production).
1220–0025	International Price Program—U.S. Export Product Information.
1220–0163	Consumer Price Index Housing Survey.
1220–0042	Report on Occupational Employment.
1220–0045	Survey of Occupational Injuries.
1220–0133	Census of Fatal Occupational Injuries.
1220–0012	Employment, Wages and Contributions Report (ES–202 Program).
1220–0032	Annual Refiling Survey.
1220–0141	Cognitive and Psychological Research.
1220–0134	Multiple Worksite Report and the Report of Federal Employment and Wages.

Affected Public: Individuals or Households, Private Sector, and State, Local and Tribal.

Total Respondents: Unchanged from current collection.

Frequency: Unchanged from current collection.

Total Responses: Unchanged from current collection.

Average Time per Response: Unchanged from current collection.

Estimated Total Burden Hours: Unchanged from current collection.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 29th day of November 2016.

Kimberley Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2016–29280 Filed 12–6–16; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–087)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington, DC 20543. Attention: Desk Officer for NASA.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA Clearance Officer, NASA Headquarters, 300 E Street SW., JF0000, Washington, DC 20546, (202) 358–2225.

SUPPLEMENTARY INFORMATION:

I. Abstract

NASA hosts/sponsors numerous events on federally owned/leased property which are open to NASA affiliates and members of the public. The events include but are not limited to meetings, conferences, briefings, public outreach activities, tours, focus groups, etc. Visitor access is substantiated by a credentialed NASA sponsor who validates the visitor's need to access a building/area, guest networking services, etc. for a specific event/purpose. Information is collected to validate identity and enable intermittent access to activities.

Currently, visitor registration is accomplished via several electronic and paper processes. The NASA Office of Protective Services is transitioning to a one-NASA process to manage access for visitors with an affiliation less than 30-days.

NASA may collect event registration information to include but not limited to a visitor's name, address, citizenship, biometric data, purpose of visit, the location to be visited, escort/sponsor name with contact data, and preferred meeting/event sessions when options are available. When parking is provided on federal owned/leased space, driver's license information as well as vehicle make/model/tag information will be collected.

When visitors/vendors are permitted to bring equipment and/or event set-up materials such as booths and displays. Information will be collected to issue property passes and coordinate equipment/property delivery as well as set-up requirements to include electrical power, Internet capability, etc.

NASA collects, stores, and secures information from individuals requiring routine and intermittent access in a manner consistent with the Constitution and applicable laws, including the Privacy Act (5 U.S.C. 552a) and the Paperwork Reduction Act.

II. Method of Collection

Electronic

III. Data

Title: The NASA Visitor Management System for Intermittent Access to NASA Hosted/Sponsored Events and Activities.

OMB Number: 2700–XXXX.

Type of Review: Existing Collection In Use Without OMB Approval.

Affected Public: Individuals.

Estimated Number of Respondents: 400,000.

Estimated Time per Response: 8 minutes.

Estimated Total Annual Public Burden Hours: 53,333.

Estimated Total Annual Public Cost: $75,080.00.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2016–29265 Filed 12–6–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (16–086)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Frances Teel, National Aeronautics and Space Administration, Mail Code JF–000, Washington DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA Clearance Officer, NASA Headquarters, 300 E Street SW., JF0000, Washington, DC 20546.

SUPPLEMENTARY INFORMATION:

I. Abstract

Contractors performing research and development are required by statutes, NASA implementing regulations, and OMB policy to submit reports of inventions, patents, data, and copyrights, including the utilization and disposition of same. The NASA New Technology Summary Report reporting form is being used for this purpose.

II. Method of Collection

NASA FAR Supplement clauses for patent rights and new technology encourage the contractor to use an electronic form and provide a hyperlink to the electronic New Technology Reporting Web (eNTRe) site *http://invention.nasa.gov.* This Web site has been set up to help NASA employees and parties under NASA funding agreements (*i.e.,* contracts, grants, cooperative agreements, and subcontracts) to report new technology information directly, via a secure Internet connection, to NASA.

III. Data

Title: NFS 1827—Patents, Data, and Copyrights.

OMB Number: 2700–0052.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit institutions.

Estimated Number of Respondents: 2,240.

Estimated Time per Response: 5 hours average.

Estimated Total Annual Burden Hours: 11,395.

Estimated Total Annual Cost: $94,093.

IV. Request for Comments

Comments are invited on—(1) whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2016–29264 Filed 12–6–16; 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 under the Antarctic Conservation Act of 1978, Public Law 95–541.

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 at Title 45 Part 670 of 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 January 6, 2017. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), 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: 2017–033

1. *Applicant:* Joseph Wilson, Penguin Films Ltd, 1 St Augustine's Lane, Bristol BS1 5DE United Kingdom.

Activity for Which Permit is Requested: Take. The applicant proposes to film killer whales (*Orcinus orca*) and minke whales (*Balaenoptera bonarensis*) in McMurdo Sound and the Ross Sea in Antarctica. Filming will be done via helicopter using long-range telephoto lenses and from the sea ice edge via an underwater camera. For the helicopter-based filming, the applicant proposes to fly at altitudes no lower than 600 vertical feet and plans to film the whales at an angle, from the side. The applicant plans to target and potentially disturb up to 60 whales over the course of one season of filming. The applicant has also applied for a commercial or education photography permit from the National Marine Fisheries Service under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*).

Location: McMurdo Sound and Ross Sea, Antarctica.

Dates: January 1—February 15, 2017.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2016–29321 Filed 12–6–16; 8:45 am]

BILLING CODE 7555–01–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 under the Antarctic Conservation Act of 1978, Public Law 95–541.

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 at Title 45 Part 670 of 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 January 6, 2017. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), 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: 2017–034

1. *Applicant:* Dr. David W. Johnston, Duke University Marine Laboratory, Beaufort, NC 28516.

Activity for Which Permit is Requested: Take; Harmful Interference; Enter Antarctic Specially Protected Area (ASPA). The applicant proposes to use unmanned aircraft systems (UAS) for photogrammetry and aerial surveys of whales and seabirds in the Antarctic Peninsula region between Charcot Island and the North Gerlache Strait, including ASPA No. 117, Avian Island, Marguerite Bay. The applicant plans to use both fixed-wing and multicopter small UAS at altitudes of 50—300 feet above the target species. Average flight times are expected to range from 12 to 35 minutes. The UAS pilots have experience appropriate for the proposed activities. The species subject to take or harmful interference as result of the proposed activity include: humpback whales (n=100 per year), minke whales (n=100 per year), Adelie penguins (n=2000 per year), Gentoo penguins (n=2000 per year), chinstrap penguins (n=500 per year), brown skua (n=50 per year), south polar skua (n=50 per year), giant petrel (n=50 per year), kelp gull (n=100 per year), blue-eyed shag (n=100 per year), snowy sheathbill (n=50 per year). The applicant currently holds a Marine Mammal Protection Act permit (14809–02) that allows for the take of the whale species in the Southern Ocean by photogrammetry and photo-identification.

Location: Antarctic Peninsula region; Torgersen Island; ASPA No. 117, Avian Island, Marguerite Bay.

Dates: January 5, 2017—March 31, 2019.

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2016–29322 Filed 12–6–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–416; NRC–2016–0236]

License Renewal for Grand Gulf Nuclear Station, Unit 1

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 No. NPF–29 to Entergy Company (Entergy or the licensee), the operator of Grand Gulf Nuclear Station, Unit 1 (GGNS). Renewed facility operating license No. NPF–29 authorizes operation of GGNS by the licensee at reactor core power levels not in excess of 4,408 megawatts thermal, in accordance with the provisions of the GGNS renewed license and technical specifications. In addition, the NRC has prepared a record of decision (ROD) that supports the NRC's decision to renew facility operating license No. NPF–29.

DATES: The license renewal of facility operating license No. NPF–29 was effective on December 1, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0236 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 Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0236. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 ''*ADAMS Public Documents*'' and then 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 in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *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: Emmanuel Sayoc, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone: 301–415–4084; email: *Emmanuel.Sayoc@nrc.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the NRC has issued renewed facility operating license No. NPF–29 to Entergy Company, the operator of GGNS. Renewed facility operating license No. NPF–29 authorizes operation of GGNS by the licensee at reactor core power levels not in excess of 4,408 megawatts thermal, in accordance with the provisions of the GGNS renewed license and technical specifications. The NRC's ROD that supports the NRC's decision to renew facility operating license No. NPF–29 is available in ADAMS under Accession No. ML16243A024. As discussed in the ROD and the final supplemental environmental impact statement (FSEIS) for GGNS, Supplement 50 to NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants Regarding Grand Gulf Nuclear Station, Unit 1,'' dated November 30, 2014 (ADAMS Accession No. ML14328A171), the NRC has considered a range of reasonable alternatives that included natural gas combined-cycle (NGCC), supercritical pulverized coal, combination of wind, solar, and NGCC, and the no action alternative. The ROD and FSEIS document the NRC decision for the environmental review that the adverse environmental impacts of license renewal for GGNS are not so great that preserving the option of license renewal for energy planning decision makers would be unreasonable.

Grand Gulf Nuclear Station, Unit 1 is a boiling water reactor located 20 miles southwest of Vicksburg, Mississippi. The application for the renewed license, ''License Renewal Application, Grand Gulf Nuclear Station, Unit 1,'' dated October 28, 2011, as supplemented by letters dated through October 3, 2016 (ADAMS Accession No. ML11308A052), complied 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 chapter 1 of title 10 of the *Code of Federal Regulations* (10 CFR), the NRC has made appropriate findings, which are set forth in the license. A public notice of the proposed issuance of the renewed license and an opportunity for a hearing was published in the **Federal Register** on December 27, 2011 (76 FR 80980).

For further details with respect to this action, see: (1) Entergy Company, license renewal application for Grand Gulf Nuclear Station, Unit 1, dated October 28, 2011, as supplemented by letters dated through October 3, 2016; (2) the NRC's safety evaluation report published on October 18, 2016 (ADAMS

Accession No. ML16288A185); (3) the NRC's final environmental impact statement (NUREG–1437, Supplement 50), for GGNS published in November 2014; and (4) the NRC's record of decision.

Dated at Rockville, Maryland, this 1st day of December, 2016.

For the U.S. Nuclear Regulatory Commission.

Jane E. Marshall,

Acting Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–29357 Filed 12–6–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–170; NRC–2012–0272]

Armed Forces Radiobiology Research Institute

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued a renewal of Facility Operating License No. R–84, held by the Armed Forces Radiobiology Research Institute (AFRRI or the licensee) for the continued operation of its AFRRI Training, Research, Isotopes Production, General Atomics (TRIGA) reactor for an additional 20 years.

DATES: The Renewed Facility Operating License No. R–84 is effective on November 30, 2016.

ADDRESSES: Please refer to Docket ID NRC–2012–0272 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 Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0272. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 ''*ADAMS Public Documents*'' and then 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, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Cindy K. Montgomery, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3398; email: *Cindy.Montgomery@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has issued renewed Facility Operating License No. R–84, held by the licensee, which authorizes continued operation of the AFRRI TRIGA reactor, located in Bethesda, Maryland. The AFRRI TRIGA reactor is a heterogeneous pool-type, natural convection, light-water cooled and shielded reactor. The renewed license authorizes the licensee to operate the AFRRI TRIGA reactor up to a steady-state power level of 1.1 megawatts thermal with pulsing capability using reactivity insertions up to 2.45% Δk/k. The renewed Facility Operating License No. R–84 will expire 20 years from its date of issuance, November 30, 2016.

The renewed facility operating license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in Chapter I of title 10 of the *Code of Federal Regulations* (10 CFR), and sets forth those findings in the renewed facility operating license. The agency afforded an opportunity for hearing in the Notice of Opportunity for Hearing published in the **Federal Register** on November 15, 2012 (77 FR 68155). The NRC received no request for a hearing or petition for leave to intervene following the notice.

The NRC staff prepared a Safety Evaluation Report related to the renewal of Facility Operating License No. R–84 and concluded, based on that evaluation, that the licensee can continue to operate the facility without endangering the health and safety of the public. The NRC staff also prepared an Environmental Assessment and Finding of No Significant Impact regarding the renewal of the facility operating license, noticed in the **Federal Register** on November 25, 2016 (81 FR 85268), and concluded that renewal of the facility operating license will not have a significant impact on the quality of the human environment.

Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS accession numbers, as indicated.

Document	ADAMS accession No.
Armed Forces Radiobiology Research Institute Renewal of Operating License R–84 for 1 MW TRIGA Research Reactor (June 24, 2004)	ML041800067
Reactor Operator Requalification Program for Armed Forces Radiobiology Research Institute (June 24, 2004)	ML041800071
Environmental Report for Armed Forces Radiobiology Research Institute (June 24, 2004)	ML041800068
Safety Analysis Report for Armed Forces Radiobiology Research Institute (AFRRI) (June 24, 2004) (redacted version)	ML101650415
Safety Analysis Report Chapters 4 and 13 for Armed Forces Radiobiology Research Institute (AFRRI) (March 4, 2010) (redacted version)	ML101650422
Request for Additional Information Regarding Financial Qualifications for the License Renewal Review (August 13, 2010)	ML102310075
Armed Forces Radiobiology Research Institute Response to Request for Additional Information dated July 19, 2010 Re: Technical Specifications (September 27, 2010) (redacted version)	ML110260024
Letter Re: Armed Forces Radiobiology Research Institute-Request for Additional Information Regarding the Application for License Renewal (TAC No. ME1587) (October 21, 2010)	ML103070121
Request for Additional Information Re: License Amendment, Separation of Byproduct Material (December 15, 2010)	ML103560456
Request for Additional Information Regarding the Application for License Renewal (February 7, 2011)	ML110460687
Armed Forces Radiobiology Research Institute—Response to Request for Additional Information Regarding the Application for License Renewal (June 20, 2011)	ML112232300

Document	ADAMS accession No.
Response to Request for Additional Information Regarding the Application for Renewal of License R–84 (September 6, 2011)	ML11269A030
Armed Forces Radiobiology Research Institute—Response to NRC Request for Additional Information Questions 14–41 and Resubmittal of Technical Specifications (October 20, 2011) (redacted version)	ML113410120
Response to Request for Additional Information Regarding the Application for License Renewal (TAC No. ME1587) (November 28, 2011)	ML11341A133
Armed Forces Radiobiology Research Institute, Technical Responses to NRC Request for Additional Information Re: License Renewal (TAC No. ME1587) (November 28, 2011) (redacted version)	ML113460085
Request For Additional Information Regarding The Application For License Renewal (TAC No. ME1587) (April 20, 2012)	ML12122A146
Response to Request for Additional Information Regarding the Application for License Renewal (TAC No. ME1587) (January 17, 2012)	ML12032A054
Request for Additional Information Regarding the Application for License Renewal (September 21, 2012)	ML12272A303
Armed Forces Radiobiology Research Institute—Response to Request for Additional Information Regarding the Application for License Renewal (TAC ME1587) (June 28, 2013)	ML13182A084
U.S. Dept of Defense, Uniformed Services University of the Health Sciences—Submittal of revised Technical Specifications, Docket 50–170 (August 27, 2014)	ML13254A064
Request for Additional Information Regarding the Renewal of Facility Operating License No. R–84 for the AFRRI TRIGA Reactor Facility (December 4, 2014)	ML14349A319
Letter from Stephen L. Miller Enclosing Revision of the Technical Specifications for the Armed Forces Radiobiology Research Institute Reactor (license R–84, docket 50–170) (March 30, 2015)	ML15093A099
Request for Additional Information Regarding the Application for License Renewal (February 9, 2016)	ML16040A310
Submittal of Technical Specifications for the Armed Forces Radiobiology Research Institute Facility (February 26, 2016)	ML16060A210
U.S. Fish and Wildlife Service, Armed Forces Radiobiology Research Institute TRIGA Research Reactor Proposed License Renewal, IPaC Trust Resources Report, (August 5, 2016)	ML16218A224
U.S. Fish and Wildlife Service, Endangered Species Consultations Frequently Asked Questions, (July 15, 2013)	ML16120A505
Response to NRR Request for Additional Information Regarding the Application for License Renewal for AFRRI Facility (August 5, 2016)	ML16232A164
U.S. Department of Defense, Armed Forces Radiobiology Research Institute (AFRRI), Submittal of Request for Additional Information Regarding the Application for License Renewal (TAC No. ME1587) (September 12, 2016)	ML16258A463
Reactor Operator Requalification Program for the AFRRI TRIGA Reactor Facility (September 12, 2016)	ML16258A464
Request for Additional Information Regarding the Application for License Renewal (TAC No. ME1587) (September 21, 2016)	ML16267A447
AFRRI Email Regarding License Renewal Application (September 26, 2016)	ML16270A541
AFRRI Email Response to Request for Additional Information for License Renewal (September 27, 2016)	ML16271A536
Letter from Stephen L. Miller Enclosing Revision of the Technical Specifications for the Armed Forces Radiobiology Research Institute Reactor (September 30, 2016)	ML16278A111
U.S. Armed Forces Radiobiology Research Institute Letter Regarding Review of Draft License R–84 (November 16, 2016)	ML16321A461
Armed Forces Radiobiology Research Institute—Issuance of Renewed Facility Operating License No. R–84 for the Armed Forces Radiobiology Research Institute Research Reactor (November 30, 2016)	ML16077A303

Dated at Rockville, Maryland, this 1st day of December, 2016.

For the Nuclear Regulatory Commission

Alexander Adams, Jr.,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–29359 Filed 12–6–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0108]

Changes to Aging Management Guidance for Various Steam Generator Components

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim staff guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing the final License Renewal Interim Staff Guidance (LR–ISG), LR–ISG–2016–01, ''Changes to Aging Management Guidance for Various Steam Generator Components.'' This LR–ISG describes changes to aging management program (AMP) XI.M19, ''Steam Generators,'' and aging management review (AMR) items for steam generator components in NUREG–1801, ''Generic Aging Lessons Learned (GALL) Report,'' Revision 2, and NUREG–1800, ''Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants'' (SRP–LR), Revision 2.

DATES: This guidance is effective on January 6, 2017.

ADDRESSES: Please refer to Docket ID NRC–2016–0108 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 Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0108. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Seung Min, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–

0001; telephone: 301–415–2045; email: *Seung.Min@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC issues LR–ISGs to communicate insights and lessons learned and to address emergent issues not covered in existing license renewal guidance documents such as the GALL Report, NUREG–1801, Revision 2 (December 2010); and the SRP–LR, NUREG–1800, Revision 2 (December 2010), which are available in ADAMS under Accession Nos. ML103490041 and ML103490036, respectively. The NRC staff and stakeholders may use the guidance in an LR–ISG document before it is incorporated into a license renewal guidance document revision. The NRC staff issues LR–ISGs in accordance with the LR–ISG Process, Revision 2 (ADAMS Accession No. ML100920158), for which a notice of availability was published in the **Federal Register** on June 22, 2010 (75 FR 35510).

The NRC staff has developed LR–ISG–2016–01 (ADAMS Accession No. ML16237A383) to describe changes to the aging management guidance for various steam generator components within the scope of part 54 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for Renewal of Operating Licenses for Nuclear Power Plants.'' Specifically, this LR–ISG addresses the changes to aging management guidance for managing: (a) Cracking due to primary water stress corrosion cracking in divider plate assemblies and tube-to-tubesheet welds, and (b) loss of material due to boric acid corrosion in steam generator heads (interior surfaces) and tubesheets (primary side). In addition, changes are made to the associated AMR items in the GALL Report and SRP–LR. This LR–ISG also revises the Final Safety Analysis Report supplement for GALL Report AMP XI.M19, ''Steam Generators'' that is documented in Table 3.0–1, ''FSAR Supplement for Aging Management of Applicable Systems'' of the SRP–LR.

On June 7, 2016, (81 FR 36612) the NRC requested public comments on draft LR–ISG–2016–01 (ADAMS Accession No. ML16102A268). The NRC received comments from the Nuclear Energy Institute by letter dated July 7, 2016 (ADAMS Accession No. ML16194A026). No other comments were submitted. The NRC considered those comments in developing the final LR–ISG. Detailed responses to the comments can be found in Appendix C of the final LR–ISG.

The final LR–ISG–2016–01 is approved for NRC staff and stakeholder use and will be incorporated into the next revision of the NRC's license renewal guidance document. These changes provide one acceptable approach for managing the associated aging effects for steam generator components within the scope of the license renewal rule (10 CFR part 54). A licensee may cite LR–ISG–2016–01 in its license renewal application until the guidance in this LR–ISG is incorporated into the license renewal guidance documents (*i.e.,* GALL Report and SRP–LR).

The staff also plans to consider the information in this LR–ISG and make corresponding changes when finalizing the aging management guidance for the subsequent license renewal period (*i.e.,* up to 80 years of operation), which is documented in draft NUREG–2191, draft ''Generic Aging Lessons Learned for Subsequent License Renewal Report'' (GALL–SLR) (ADAMS Accession Nos. ML15348A111 and ML15348A153), and draft NUREG–2192, draft ''Standard Review Plan for Review of Subsequent License Renewal for Nuclear Power Plants'' (SRP–SLR) (ADAMS Accession No. ML15348A265).

II. Congressional Review Act

This LR–ISG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

III. Backfitting

The NRC intends to use the guidance in this LR–ISG when reviewing current and future license renewal applications. Issuance of this final LR–ISG does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule). As discussed in the ''Backfitting'' section of the final LR–ISG–2016–01, the backfitting provisions in 10 CFR 50.109 are not applicable to an applicant for a renewed license. Therefore, issuance of this LR ISG would not constitute backfitting for licensees currently in the license renewal process as defined in 10 CFR 50.109(a)(1). This guidance is nonbinding and the LR–ISG does not require current holders of renewed licenses to take any action (*i.e.,* programmatic or plant hardware changes for managing the associated aging effects for components within the scope of this LR–ISG). The current holders of renewed licenses could treat the information presented in this LR–ISG as ''operating experience'' information and consider this information to ensure that relevant AMPs are, and will remain, effective. However, the NRC could also use the LR–ISG in evaluating voluntary, licensee-initiated changes to previously approved AMPs.

Dated at Rockville, Maryland, this 30th day of November, 2016.

For the Nuclear Regulatory Commission.

Benjamin G. Beasley,

Acting Deputy Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–29363 Filed 12–6–16; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79437; File No. SR–BatsBZX–2016–78]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Non-Substantive Changes to the Fee Schedule

December 1, 2016.

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 November 29, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to make several non-substantive changes to the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to Exchange Rules 15.1(a) and (c).

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make certain clarifying and non-substantive changes to its fee schedule in order to improve formatting, eliminate certain redundancies, increase overall readability, and provide users with straightforward descriptions to augment overall comprehensibility and usability of the existing fee schedule. The Exchange notes that these changes are purely clerical and do not substantively amend any fee or rebate, nor do they alter the manner in which the Exchange assesses fees or calculates rebates. The proposed changes are simply intended to provide greater transparency to market participants regarding how the Exchange assesses fees and calculates rebates. Specifically, the Exchange proposes to:

- Alphabetize defined terms under the ''Definitions'' section; [6]
- capitalize the title of the column setting forth each tier's rate under footnotes 1, 2, 3, 4, 11, 12, 13, and 14;
- amend the name of footnote 2 from ''Tiers'' to ''Tier'' to connote the footnote's single tier;
- amend the title of the first column of footnote 1, 2, 3, and 14 to simply state ''Tier'' as the deleted language is redundant with the respective tier's title or with the description of the tier's criteria;
- amend the title of the column setting forth the tier's rate under footnote 13 to simply state ''Fee Per Share to Remove'' or ''Rebate Per Share to Add'' as applicable. Renaming these [sic] column is intended to clearly indicate whether the footnote provides a fee and/or a rebate, and whether that enhanced pricing applies to orders which add or remove liquidity. In renaming these columns, the Exchange also proposes to remove certain other descriptive language as such language is redundant and set forth in the tier's title and list of its applicable fee codes;
- amend the name under first column of the tiers listed under footnotes 2, 3, 4, 11, 12, 13 and 14 to simply state ''Tier'' or ''Tier 1'', Tier 2'', etc.;
- replace the phrases ''is equal to or greater than'', ''is at least'', ''of at least'' and ''that is . . . or more'' with ''≥'' in all required criteria cells throughout the fee schedule; and
- amend the description of the required criteria under the third column of the tiers to begin with ''Member has an'' where applicable. Amending this description is intended to harmonize the format of the tier's criteria with its affiliate exchanges.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[7] Specifically, the Exchange believes that the proposed rule change is consistent with Sections 6(b)(4) of the Act,[8] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange believes that the proposed changes are reasonable and equitable because they are intended to simplify the Exchange's fee schedule and provide greater transparency to market participants regarding how the Exchange assesses fees and calculates rebates. The Exchange notes that these changes are purely clerical and do not substantively amend any fee or rebate, nor do they alter the manner in which the Exchange assesses fees or calculates rebates. The Exchange also believes that the proposal is non-discriminatory because it applies uniformly to all Members. Finally, the Exchange believes that the proposed changes will make the fee schedule clearer and eliminate potential investor confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. To the contrary, the Exchange believes that the proposed rule change will not impose any burden on competition as the changes are purely clerical and do not amend any fee or rebate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and paragraph (f) of Rule 19b–4 thereunder.[10] 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–BatsBZX–2016–78 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[6] The Exchange does not proposes to alphabetize the definitions under the Market Data section of its fee schedule as those terms are generally grouped with similar terms.

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–78. 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 Web site (*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 Web site 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 the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBZX–2016–78, and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29284 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79446; File No. SR–BX–2016–065]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Pilot Period for the Retail Price Improvement Program Until December 1, 2017

December 1, 2016.

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 November 29, 2016, NASDAQ BX, Inc. (''BX'' or ''Exchange'') 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 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 seeks to extend the pilot period for the Exchange's Retail Price Improvement (''RPI'') Program (the ''Program''), which is set to expire on December 1, 2016, for a period of one year, to expire on December 1, 2017.

The Exchange has designated December 1, 2016 as the date the proposed rule change becomes effective.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[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 purpose of this filing is to extend the pilot period of the RPI Program,[3] currently scheduled to expire on December 1, 2016 for an additional year, until December 1, 2017.

Background

In November 2014, the Commission approved the RPI Program on a pilot basis.[4] The Program is designed to attract retail order flow to the Exchange, and allow such order flow to receive potential price improvement. The Program is currently limited to trades occurring at prices equal to or greater than $1.00 per share. Under the Program, a new class of market participant called a Retail Member Organization (''RMO'') is eligible to submit certain retail order flow (''Retail Orders'')[5] to the Exchange. BX members (''Members'') are permitted to provide potential price improvement for Retail Orders in the form of non-displayed interest that is priced more aggressively than the Protected National Best Bid or Offer (''Protected NBBO'').[6]

The Program was approved by the Commission on a pilot basis running one-year from the date of implementation.[7] The Commission approved the Program on November 28, 2014.[8] The Exchange implemented the

[3] Securities Exchange Act Release No. 73702 (November 28, 2014), 79 FR 72049 (December 4, 2014) (''RPI Approval Order'') (SR–BX–2014–048).

[4] *See id.*

[5] A ''Retail Order'' is defined in BX Rule 4780(a)(2) by referencing BX Rule 4702, and BX Rule 4702(b)(6) says it is an order type with a non-display order attribute submitted to the Exchange by a RMO. A Retail Order must be an agency order, or riskless principal order that satisfies the criteria of FINRA Rule 5320.03. The Retail Order must reflect trading interest of a natural person with no change made to the terms of the underlying order of the natural person with respect to price (except in the case of a market order that is changed to a marketable limit order) or side of market and that does not originate from a trading algorithm or any other computerized methodology.

[6] The term Protected Quotation is defined in Chapter XII, Sec. 1(19) and has the same meaning as is set forth in Regulation NMS Rule 600(b)(58). The Protected NBBO is the best-priced protected bid and offer. Generally, the Protected NBBO and the national best bid and offer (''NBBO'') will be the same. However, a market center is not required to route to the NBBO if that market center is subject to an exception under Regulation NMS Rule 611(b)(1) or if such NBBO is otherwise not available for an automatic execution. In such case, the Protected NBBO would be the best-priced protected bid or offer to which a market center must route interest pursuant to Regulation NMS Rule 611.

[7] *See* RPI Approval Order, *supra* note 3 at 72053.

[8] *Id.* at 72049.

Program on December 1, 2014 and the pilot has since been extended for a year with it now scheduled to end on December 1, 2016.[9]

Proposal To Extend the Operation of the Program

The Exchange established the RPI Program in an attempt to attract retail order flow to the Exchange by potentially providing price improvement to such order flow. The Exchange believes that the Program promotes competition for retail order flow by allowing Exchange members to submit Retail Price Improvement Orders (''RPI Orders'') [10] to interact with Retail Orders. Such competition has the ability to promote efficiency by facilitating the price discovery process and generating additional investor interest in trading securities, thereby promoting capital formation. The Exchange believes that extending the pilot is appropriate because it will allow the Exchange and the Commission additional time to analyze data regarding the Program that the Exchange has committed to provide.[11] As such, the Exchange believes that it is appropriate to extend the current operation of the Program.[12] Through this filing, the Exchange seeks to extend the current pilot period of the Program until December 1, 2017.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[13] in general, and with Section 6(b)(5) of the Act,[14] in particular, in that it is designed 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 Exchange believes that extending the pilot period for the RPI Program is consistent with these principles because the Program is reasonably designed to attract retail order flow to the exchange environment, while helping to ensure that retail investors benefit from the better price that liquidity providers are willing to give their orders. Additionally, as previously stated, the competition promoted by the Program may facilitate the price discovery process and potentially generate additional investor interest in trading securities. The extension of the pilot period will allow the Commission and the Exchange to continue to monitor the Program for its potential effects on public price discovery, and on the broader market structure.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change extends an established pilot program for one year, thus allowing the RPI Program to enhance competition for retail order flow and contribute to the public price discovery process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) [16] thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.[17]

A proposed rule change filed under Rule 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) [18] 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 requested that the Commission waive the 30-day operative delay period. The Exchange states that waiving the operative delay would allow the pilot period to continue uninterrupted, which the Exchange argues would be beneficial to market participants and would help to eliminate the potential for investor confusion.

The Commission believes that waiver of the 30-day operative delay period is consistent with the protection of investors and the public interest. Specifically, the Commission believes that the proposal would allow the RPI Program to continue uninterrupted and to provide additional time for data about the program to be generated and analyzed. For these reasons, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, and designates the proposed rule change to be operative upon filing with the Commission.[19]

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.[20]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2016–065 on the subject line.

[9] *See* Securities Exchange Act Release No. 76490 (November 20, 2015), 80 FR 74165 (November 27, 2015) (SR–BX–2015–073).

[10] A Retail Price Improvement Order is defined in BX Rule 4780(a)(3) by referencing BX Rule 4702 and BX Rule 4702(b)(5) says that it is as an order type with a non-display order attribute that is held on the Exchange Book in order to provide liquidity at a price at least $0.001 better than the NBBO through a special execution process described in Rule 4780.

[11] *See* RPI Approval Order, *supra* note 3 at 72051.

[12] Concurrently with this filing, the Exchange has submitted a request for an extension of the exemption under Regulation NMS Rule 612 previously granted by the Commission that permits it to accept and rank the RPI orders in sub-penny increments. *See* Letter from Jeffrey S. Davis, Vice President and Deputy General Counsel and Secretary, NASDAQ BX, Inc. to Brent J. Fields, Secretary, Securities and Exchange Commission dated November 22, 2016.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6).

[17] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78s(b)(3)(C).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–065. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–065 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29291 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[21] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79438; File No. SR–BatsEDGX–2016–67]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Non-Substantive Changes to the Equity Options Fee Schedule

December 1, 2016.

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 November 18, 2016, Bats EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to make several non-substantive changes to the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to Exchange Rules 15.1(a) and (c).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its fee schedule applicable to the Exchange's equity options platform (''EDGX Options'') to make certain clarifying and non-substantive changes to its fee schedule in order to improve formatting, eliminate certain redundancies, increase overall readability, and provide users with straightforward descriptions to augment overall comprehensibility and usability of the existing fee schedule. The Exchange notes that these changes are purely clerical and do not substantively amend any fee or rebate, nor do they alter the manner in which the Exchange assesses fees or calculates rebates. The proposed changes are simply intended to provide greater transparency to market participants regarding how the Exchange assesses fees and calculates rebates. Specifically, the Exchange proposes to:

• Alphabetize defined terms under the ''Definitions'' section;[6]

• amend footnote 3 to include the word ''Tier'' at the end of its title;

• amend the title of the column setting forth each tier's rate to simply state ''Fee Per Contract'', ''Rebate Per Contract'' or ''Fee/Rebate Per Contract''), as applicable. Renaming these columns is intended to clearly indicate whether the footnote provides a fee and/or a rebate. In renaming these columns, the Exchange also proposes to remove certain other descriptive language as such language is redundant and set forth in the tier's title and list of its applicable fee codes;

• ensure each tier requiring multiple criteria is conjoined using ''; and'' to clarify that all of a tier's criteria must be satisfied to receive the applicable rate;

• replace the phrase ''equal to or greater than'' with ''≥'' in all required criteria cells under footnote 1, 2, 3, and 4.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] The Exchange does not propose to alphabetize the definitions under the Market Data section of its fee schedule as those terms are generally grouped with similar terms.

requirements of Section 6 of the Act.[7] Specifically, the Exchange believes that the proposed rule change is consistent with Sections 6(b)(4) of the Act of the Act [sic],[8] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange believes that the proposed changes are reasonable and equitable because they are intended to simplify the Exchange's fee schedule and provide greater transparency to market participants regarding how the Exchange assesses fees and calculates rebates. The Exchange notes that these changes are purely clerical and do not substantively amend any fee or rebate, nor do they alter the manner in which the Exchange assesses fees or calculates rebates. The Exchange also believes that the proposal is non-discriminatory because it applies uniformly to all Members. Finally, the Exchange believes that the proposed changes will make the fee schedule clearer and eliminate potential investor confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. To the contrary, the Exchange believes that the [sic] will not impose any burden on competition as the changes are purely clerical and do not amend and [sic] fee or rebate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and paragraph (f) of Rule 19b–4 thereunder.[10] 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-BatsEDGX–2016–67 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–BatsEDGX–2016–67. 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 Web site (*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 Web site 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 the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGX–2016–67, and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Lynn Powalski,

Deputy Secretary.

[FR Doc. 2016–29282 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79441; File No. SR–C2–2016–023]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Penny Pilot Program

December 1, 2016.

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 November 23, 2016, C2 Options Exchange, Incorporated (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the operation of Penny Pilot Program through June 30, 2017. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

C2 Options Exchange, Incorporated

Rules

* * * * *

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

Rule 6.4. Minimum Increments for Bids and Offers

The Board of Directors may establish minimum quoting increments for options traded on the Exchange. When the Board of Directors determines to change the minimum increments, the Exchange will designate such change as a stated policy, practice, or interpretation with respect to the administration of this Rule within the meaning of subparagraph (3)(A) of subsection 19(b) of the Exchange Act and will file a rule change for effectiveness upon filing with the Commission. Until such time as the Board of Directors makes a change to the minimum increments, the following minimum increments shall apply to options traded on the Exchange:

(1) No change.

(2) No change.

(3) The decimal increments for bids and offers for all series of the option classes participating in the Penny Pilot Program are: $0.01 for all option series quoted below $3 (including LEAPS), and $0.05 for all option series $3 and above (including LEAPS). For QQQQs, IWM, and SPY, the minimum increment is $0.01 for all option series. The Exchange may replace any option class participating in the Penny Pilot Program that has been delisted with the next most actively-traded, multiply-listed option class, based on national average daily volume in the preceding six calendar months, that is not yet included in the Pilot Program. Any replacement class would be added on the second trading day following [July 1, 2016]*January 1, 2017.* The Penny Pilot shall expire on [December 31, 2016]*June 30, 2017.* Also, for so long as SPDR options (SPY) and options on Diamonds (DIA) participate in the Penny Pilot Program, the minimum increments for Mini-SPX Index Options (XSP) and options on the Dow Jones Industrial Average (DJX), respectively, may be $0.01 for all option series quoting less than $3 (including LEAPS), and $0.05 for all option series quoting at $3 or higher (including LEAPS).

(4) No change.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*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 Penny Pilot Program (the ''Pilot Program'') is scheduled to expire on December 31, 2016. C2 proposes to extend the Pilot Program until June 30, 2017. C2 believes that extending the Pilot Program will allow for further analysis of the Pilot Program and a determination of how the Pilot Program should be structured in the future.

During this extension of the Pilot Program, C2 proposes that it may replace any option class that is currently included in the Pilot Program and that has been delisted with the next most actively traded, multiply listed option class that is not yet participating in the Pilot Program (''replacement class''). Any replacement class would be determined based on national average daily volume in the preceding six months,[5] and would be added on the second trading day following January 1, 2017. C2 will announce to its Trading Permit Holders by circular any replacement classes in the Pilot Program. The Exchange notes that it intends to utilize the same parameters to prospective replacement classes as was originally approved.

C2 is specifically authorized to act jointly with the other options exchanges participating in the Pilot Program in identifying any replacement class.

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 facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In particular, the proposed rule change allows for an extension of the Pilot Program for the benefit of market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Pilot Program, the proposed rule change will allow for further analysis of the Pilot Program and a determination of how the Program shall be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. In addition, the Exchange has been authorized to act jointly in extending the Pilot Program and believes the other exchanges will be filing similar extensions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6)[10] thereunder. Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if

[5] The month immediately preceding a replacement class's addition to the Pilot Program (*i.e.,* December) would not be used for purposes of the six-month analysis. Thus, a replacement class to be added on the second trading day following January 1, 2017 would be identified based on The Option Clearing Corporation's trading volume data from June 1, 2016 through November 30, 2016.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number* SR–C2–2016–023 *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–C2–2016–023. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2016–023 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Brent J. Fields.

Secretary.

[FR Doc. 2016–29286 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79450; File No. SR-BatsBZX–2016–80]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of Proposed Rule Changes to BZX Rule 14.11, Other Securities, and BZX Rule 14.12, Failure To Meet Listing Standards

December 1, 2016.

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 November 18, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') 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 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 filed a proposal to amend the listing rules for exchange-traded products in Bats Rule 14.11 (''ETPs'') to add additional continued listing standards as well as a related amendment to Rule 14.12, entitled ''Failure to Meet Listing Standards.'' The Exchange is also proposing to make certain cleanup changes throughout Rule 14.11 in order to make the rule text more clear.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the listing rules for ETPs in Bats Rule 14.11, entitled ''Other Securities,'' to add additional continued listing standards as well as a related amendment to Rule 14.12, entitled ''Failure to Meet Listing Standards.'' The Exchange is also proposing to make certain cleanup changes throughout Rule 14.11 in order to make the rule text more clear.

The proposed rule changes are being made at the request of and as part of discussions with the Commission. Based on concerns about certain of the ETP listing rules applying only on an initial basis, SEC staff has requested that the Exchange adopt certain additional continued listing standards for ETPs. As a result, the proposed amendment reflects guidance provided by SEC staff to clarify that most initial listing standards, as well as certain representations (''Continued Listing Representations'') included in Exchange rule filings pursuant to Section 19(b) of the Act [3] to list an ETP on the Exchange (''Rule Filing''), are also considered continued listing standards. Continued Listing Representations will also be required to be maintained on a continuous basis and include any of the representations regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b).

dissemination and availability of index and intraday indicative values (as applicable), and the applicability of Exchange rules and surveillance procedures made in any filing to list a series of ETPs.

The proposed rule changes require that ETPs listed by the Exchange without a Rule Filing must maintain the initial index or reference asset criteria, among other requirements, on both an initial listing and continual basis. For example, in the case of a domestic equity index, these criteria generally include: (a) Stocks with 90% of the weight of the index must have a minimum market value of at least $75 million; (b) stocks with 70% of the weight of the index must have a minimum monthly trading volume of at least 250,000 shares; (c) the most heavily weighted component cannot exceed 30% of the weight of the index, and the five most heavily weighted stocks cannot exceed 65%; (d) there must be at least 13 stocks in the index; and (e) all securities in the index must be listed in the U.S. Such requirements are currently only applicable on an initial listing basis, but the proposal would require that such criteria be met on a continual basis as well. The Exchange is also proposing similar changes as it relates to the comparable criteria for international indexes, fixed-income indexes, indexes with a combination of components, and other underlying reference assets. Where an ETP fails to meet the proposed applicable continued listing requirements, the Exchange would, generally, initiate delisting proceedings pursuant to Rule 14.12.

If an ETP is listed on the Exchange pursuant to a Rule Filing, this proposed rule change would require that the issuer of the security comply on an ongoing basis with any Continued Listing Representations, which include any of the representations in the rule filing regarding the index composition, the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index and intraday indicative values (as applicable), and the applicability of Exchange rules and surveillance procedures made in any filing to list a series of ETPs. As proposed, where an ETP fails to meet the Continued Listing Representations, the Exchange would initiate delisting proceedings pursuant to Rule 14.12.

The Exchange is also proposing to modify its rules such that issuers of securities listed under Rule 14.11 would be required to provide the Exchange with prompt notification after an Executive Officer [4] of the [sic] becomes aware of any noncompliance. In addition, while listed ETPs are currently subject to the delisting process in Rule 14.12, the rules will be clarified to make this explicit. As proposed, Rule 14.12 will also be clarified to make explicit that an ETP that it is deficient under one or more listing standards may submit a plan to regain compliance to the Listing Qualifications Department. In this regard, the Exchange proposes to allow issuers of ETPs 45 calendar days to submit such a plan, which is consistent with deficiencies from most other rules that allow issuers to submit a plan to regain compliance.[5] Exchange staff will review the plan and may grant a limited period of time for the ETP to regain compliance as permitted under Rule 14.12. If Exchange staff does not accept the plan, a Staff Delisting Determination will be issued, which could be appealed to a Hearings Panel pursuant to Rule 14.12(h).

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [6] in general and Section 6(b)(5) of the Act [7] in particular in that it is designed 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 proposed rule changes accomplish these objectives by enhancing the current continued listing standards by clarifying that most initial listing standards, as well as Continued Listing Representations, are considered continued listing standards. Additionally, the Exchange is proposing to require issuers to provide the Exchange with prompt notification after an Executive Officer of the [sic] becomes aware of any noncompliance and to clarify that deficiencies will be subject to potential trade halts and delisting proceedings pursuant to Rule 14.12. The Exchange believes that these amendments will enhance the Exchange's listing rules, thereby serving to improve the national market system and protect investors and the public interest.

The Exchange does not believe that the cleanup changes have any impact on the reasonable and equitable and not unfairly discriminatory nature of the proposal.

For these reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, as amended. The Exchange believes that the proposed rule change to amend Rule 14.11 related to the listing of ETPs, the notification requirement in Rule 14.11(a), and the proposed related amendments to Rule 14.12 will have no impact on competition. Furthermore, since Commission staff has provided the same guidance regarding ETP continued listing requirements to all listing exchanges, the Exchange believes that there will be no effect on competition.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[4] As defined in Rule 14.10(c)(1)(A), the term ''Executive Officer'' means those officers covered in Rule 16a–1(f) under the Act.

[5] The Exchange notes that the following deficiencies are allowed 45 calendar days to submit a plan to regain compliance: Deficiencies from the standards of Rules 14.10(f)(3) (Quorum), 14.10(h) (Review of Related Party Transactions), 14.10(i) (Shareholder Approval), 14.6(c)(3) (Auditor Registration), 14.7 (Direct Registration Program), 14.10(d) (Code of Conduct), 14.10(e)(1)(D)(v) (Quorum of Limited Partnerships), 14.10(e)(1)(D)(vii) (Related Party Transactions of Limited Partnerships), or 14.10(j) (Voting Rights).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(5).

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-BatsBZX–2016–80 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR-BatsBZX–2016–80. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BatsBZX–2016–80 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29294 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IA–4580; File No. 803–00235]

UBS Financial Services Inc.; Notice of Application

December 1, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an exemptive order under section 206A of the Investment Advisers Act of 1940 (''Advisers Act'') providing an exemption from the written disclosure and consent requirements of section 206(3).

APPLICANT: UBS Financial Services Inc. (''Applicant'').

RELEVANT ADVISERS ACT SECTIONS: Exemption requested under section 206A from the written disclosure and consent requirements of section 206(3).

SUMMARY OF APPLICATION: Applicant requests that the Commission issue an order under section 206A exempting it and Future Advisers (as defined below) from the written disclosure and consent requirements of section 206(3) with respect to principal transactions with nondiscretionary advisory client accounts.

FILING DATES: The application was filed on November 22, 2016.

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 December 27, 2016, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Advisers Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicant, Laura E. Flores and Steven W. Stone, Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Ave. NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Robert Shapiro, Senior Counsel, at (202) 551–7758 (Chief Counsel's Office, Division of Investment Management) or Melissa Harke, Senior Special Counsel, at (202) 551–6787 (Investment Adviser Regulation Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site at *http://www.sec.gov/rules/iareleases.shtml* or by calling (202) 551–8090.

Applicant seeks relief from the written disclosure and consent requirements of section 206(3) of the Advisers Act that would be similar to relief currently provided by Advisers Act rule 206(3)–3T (the ''Rule''), which will expire by its terms on December 31, 2016. The relief sought by Applicant, if granted, would be subject to conditions similar to those under the Rule, as well as certain revised or additional conditions.

Applicant's Representations

1. The Applicant is registered as an investment adviser with the Commission and is a registered broker-dealer. The Applicant is a subsidiary of UBS AG, a diversified financial services company with operations around the world. The Applicant offers a number of advisory programs, including the UBS Strategic Advisor Program (the ''Program''), a nondiscretionary advisory program.

2. In 2007, many of the Applicant's fee-based brokerage accounts were converted to nondiscretionary advisory accounts in the Program, following the invalidation of former rule 202(a)(11)–1 under the Advisers Act. When these accounts had been fee-based brokerage accounts, the Applicant, in its capacity as a broker-dealer, engaged in principal transactions with its customers in accordance with applicable law. The Applicant currently relies on the Rule to engage in principal transactions with its client accounts in the Program.

3. The Applicant currently has approximately 115,982 client accounts enrolled in the Program. Those accounts have approximately $65 billion in assets under management as of September 20, 2016. In the period January 1, 2015 through December 31, 2015, 11,619 trades were effected in reliance on the Rule in the Program. Approximately 66% percent of the trades done in reliance on the Rule in this period were purchases by client accounts; the average purchase was approximately $109,838. Approximately 34% percent of the trades done in reliance on the Rule in this period were sales from client accounts; the average sale was approximately $105,022.

4. As permitted under the Rule, the Applicant has engaged in principal trades in investment-grade fixed income securities underwritten by the Applicant or an affiliate.

5. The Applicant acknowledges that the Order, if granted, would not be construed as relieving in any way the Applicant from acting in the best interests of an advisory client, including fulfilling the duty to seek the best execution for the particular transaction for the advisory client; nor shall it relieve the Applicant from any obligation that may be imposed by sections 206(1) or (2) of the Advisers Act or by other applicable provisions of the federal securities laws or applicable FINRA rules.

Applicant's Legal Analysis

1. Section 206(3) provides that it is unlawful for any investment adviser, directly or indirectly, acting as principal for its own account, knowingly to sell any security to or purchase any security from a client, without disclosing to the client in writing before the completion of the transaction the capacity in which the adviser is acting and obtaining the client's consent to the transaction. Rule 206(3)–3T deems an investment adviser to be in compliance with the provisions of section 206(3) of the Advisers Act when the investment adviser, or a person controlling, controlled by, or under common control with the investment adviser, acting as principal for its own account, sells to or purchases from an advisory client any security, provided that the investment adviser complies with the conditions of the Rule.

2. Rule 206(3)–3T requires, among other things, that the investment adviser obtain a client's written, revocable consent prospectively authorizing the adviser, directly or indirectly, acting as principal for its own account, to sell any security to or purchase any security from the client. The consent must be obtained after the adviser provides the client with written disclosure about: (i) The circumstances under which the investment adviser may engage in principal transactions with the client; (ii) the nature and significance of the conflicts the investment adviser has with its client's interests as a result of those transactions; and (iii) how the investment adviser addresses those conflicts. The investment adviser also must provide trade-by-trade disclosure to the client, before the execution of each principal transaction, of the capacity in which the adviser may act with respect to the transaction, and obtain the client's consent (which may be written or oral) to the transaction. The Rule is available only to an investment adviser that is also a broker-dealer registered under section 15 of the Securities Exchange Act of 1934 (''Exchange Act'') and may only be relied upon with respect to a nondiscretionary account that is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member. Rule 206(3)–3T is not available for principal transactions if the investment adviser or a person who controls, is controlled by, or is under common control with the adviser (''control person'') is the issuer or is an underwriter of the security, except that an adviser may rely on the Rule for trades in which the adviser or a control person is an underwriter of non-convertible investment-grade debt securities.

3. The investment adviser also must provide to the client a trade confirmation that, in addition to the requirements of rule 10b–10 under the Exchange Act, includes a conspicuous, plain English statement informing the client that the investment adviser disclosed to the client before the execution of the transaction that the investment adviser may act as principal in connection with the transaction, that the client authorized the transaction, and that the investment adviser sold the security to or bought the security from the client for its own account. The investment adviser also must deliver to the client, at least annually, a written statement listing all transactions that were executed in the account in reliance on the Rule, including the date and price of each transaction.

4. Rule 206(3)–3T is scheduled to expire on December 31, 2016. Upon expiration, the Applicant would be required to provide trade-by-trade written disclosure to each nondiscretionary advisory client with whom the Applicant sought to engage in a principal transaction in accordance with section 206(3). The Applicant submits that its nondiscretionary clients, through the Applicant's current reliance on the Rule, have had access to the Applicant's inventory through principal transactions for a number of years, and expect to continue to have such access in the future. The Applicant believes that engaging in principal transactions with its clients provides certain benefits to its clients, including access to securities of limited availability, such as municipal bonds, and that the written disclosure and client consent requirements of section 206(3) act as an operational barrier to its ability to engage in principal trades with its clients, especially when the transaction involves securities of limited availability.

5. Unless the Applicant is provided an exemption from the written disclosure and client consent requirements of section 206(3), Applicant believes that it will be unable to provide the same range of services and access to the same types of securities to its nondiscretionary advisory clients as it currently is able to provide to clients under the Rule.

6. The Applicant notes that, if the requested relief is granted, it will remain subject to the fiduciary duties that are generally enforceable under sections 206(1) and 206(2) of the Advisers Act, which, in general terms, require the Applicant to: (i) Disclose material facts about the advisory relationship to its clients; (ii) treat each client fairly; and (iii) act only in the best interests of its client, disclosing conflicts of interest when present and obtaining client consent to arrangements that present such conflicts.

7. The Applicant further notes that, in its capacity as a broker-dealer with respect to these accounts, it will remain subject to a comprehensive set of Commission and FINRA regulations that apply to the relationship between a broker-dealer and its customer in addition to the fiduciary duties an adviser owes a client. These rules require, among other things, that the Applicant deal fairly with its customers, seek to obtain best execution of customer orders, and make only suitable recommendations. These obligations are designed to promote business conduct that protects customers from abusive practices that may not necessarily be fraudulent, and to protect against unfair prices and excessive commissions. Specifically, these provisions, among other things, require that the prices charged by the Applicant be reasonably related to the prevailing market, and limit the commissions and mark-ups the Applicant can charge. Additionally, these obligations require that the Applicant have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer, based on information obtained through reasonable diligence.

8. The Applicant requests that the Commission issue an Order pursuant to section 206A exempting it from the written disclosure and consent requirements of section 206(3) only with respect to client accounts in the Program and any similar nondiscretionary program to be created in the future. The Applicant also requests that the Commission's Order

apply to future investment advisers controlling, controlled by, or under common control with the Applicant (''Future Advisers''). Any Future Adviser relying on any Order granted pursuant to the application will comply with the terms and conditions stated in the application.[1]

Applicant's Conditions

The Applicant agrees that any Order granting the requested relief will be subject to the following conditions:

1. The Applicant will exercise no ''investment discretion'' (as such term is defined in section 3(a)(35) of the Exchange Act), except investment discretion granted by the advisory client on a temporary or limited basis,[2] with respect to the client's account.

2. The Applicant will not trade in reliance on this Order any security for which the Applicant or any person controlling, controlled by, or under common control with the Applicant is the issuer, or, at the time of the sale, an underwriter (as defined in section 202(a)(20) of the Advisers Act).

3. The Applicant will not directly or indirectly require the client to consent to principal trading as a condition to opening or maintaining an account with the Applicant.

4. The advisory client has executed a written revocable consent prospectively authorizing the Applicant directly or indirectly to act as principal for its own account in selling any security to or purchasing any security from the advisory client. The advisory client's written consent must be obtained through a signature or other positive manifestation of consent that is separate from or in addition to the signature indicating the client's consent to the advisory agreement. The separate or additional signature line or alternative means of expressing consent must be preceded immediately by prominent, plain English disclosure containing either: (a) An explanation of: (i) The circumstances under which the Applicant directly or indirectly may engage in principal transactions; (ii) the nature and significance of conflicts with its client's interests as a result of the transactions; and (iii) how the Applicant addresses those conflicts; or (b) a statement explaining that the client is consenting to principal transactions, followed by a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific page or pages on which such disclosure is located; provided, however, that if the Applicant requires time to modify its electronic systems to provide the specific page cross-reference required by clause (b), the Applicant may, while updating such electronic systems, and for no more than 90 days from the date of the Order, instead provide a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific section in such document in which such disclosure is located. *Transition provision:* To the extent that the Applicant obtained fully informed written revocable consent from an advisory client for purposes of rule 206(3)–3T(a)(3) prior to the date of this Order, the Applicant may rely on this Order with respect to such client without obtaining additional prospective consent from such client.

5. The Applicant, prior to the execution of each transaction in reliance on this Order, will: (a) Inform the advisory client, orally or in writing, of the capacity in which it may act with respect to such transaction; and (b) obtain consent from the advisory client, orally or in writing, to act as principal for its own account with respect to such transaction.

6. The Applicant will send a written confirmation at or before completion of each such transaction that includes, in addition to the information required by rule 10b–10 under the Exchange Act, a conspicuous, plain English statement informing the advisory client that the Applicant: (a) Disclosed to the client prior to the execution of the transaction that the Applicant may be acting in a principal capacity in connection with the transaction and the client authorized the transaction; and (b) sold the security to, or bought the security from, the client for its own account.

7. The Applicant will send to the client, no less frequently than annually, written disclosure containing a list of all transactions that were executed in the client's account in reliance upon this Order, and the date and price of each such transaction.

8. The Applicant is a broker-dealer registered under section 15 of the Exchange Act and each account for which the Applicant relies on this Order is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member.

9. Each written disclosure required as a condition to this Order will include a conspicuous, plain English statement that the client may revoke the written consent referred to in Condition 4 above without penalty at any time by written notice to the Applicant in accordance with reasonable procedures established by the Applicant, but in all cases such revocation must be given effect within 5 business days of the Applicant's receipt thereof.

10. The Applicant will maintain records sufficient to enable verification of compliance with the conditions of this Order. Such records will include, *without limitation:* (a) Documentation sufficient to demonstrate compliance with each disclosure and consent requirement under this Order; (b) in particular, documentation sufficient to demonstrate that, prior to the execution of each transaction in reliance on this Order, the Applicant informed the advisory client of the capacity in which it may act with respect to the transaction and that it received the advisory client's consent (if the Applicant informs the client orally of the capacity in which it may act with respect to such transaction or obtains oral consent, such records may, for example, include recordings of telephone conversations or contemporaneous written notations); and (c) documentation sufficient to enable assessment of compliance by the Applicant with sections 206(1) and (2) of the Advisers Act in connection with its reliance on this Order.[3] In each case, such records will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

11. The Applicant will adopt written compliance policies and procedures reasonably designed to ensure, and the Applicant's chief compliance officer will monitor, the Applicant's

[1] All entities that currently intend to rely on any order granted pursuant to the application are named as Applicants.

[2] Discretion is considered to be temporary or limited for purposes of this condition when the investment adviser is given discretion: (i) As to the price at which or the time to execute an order given by a client for the purchase or sale of a definite amount or quantity of a specified security; (ii) on an isolated or infrequent basis, to purchase or sell a security or type of security when a client is unavailable for a limited period of time not to exceed a few months; (iii) as to cash management, such as to exchange a position in a money market fund for another money market fund or cash equivalent; (iv) to purchase or sell securities to satisfy margin requirements; (v) to sell specific bonds and purchase similar bonds in order to permit a client to take a tax loss on the original position; (vi) to purchase a bond with a specified credit rating and maturity; and (vii) to purchase or sell a security or type of security limited by specific parameters established by the client. *See, e.g., Temporary Rule Regarding Principal Trades with Certain Advisory Clients,* Investment Advisers Act Release No. 2653 (Sept. 24, 2007) at n. 31.

[3] For example, under sections 206(1) and (2), an adviser may not engage in any transaction on a principal basis with a client that is not consistent with the best interests of the client or that subrogates the client's interests to the adviser's own. *Cf.* Investment Advisers Act Release No. 2106 (Jan. 31, 2003) (adopting Rule 206(4)–6).

compliance with the conditions of this Order. The Applicant's chief compliance officer will, on at least a quarterly basis, conduct testing reasonably sufficient to verify such compliance. Such written policies and procedures, monitoring and testing will address, *without limitation:* (a) Compliance by the Applicant with its disclosure and consent requirements under this Order; (b) the integrity and operation of electronic systems employed by the Applicant in connection with its reliance on this Order; (c) compliance by the Applicant with its recordkeeping obligations under this Order; and (d) whether there is any evidence of the Applicant engaging in ''dumping'' in connection with its reliance on this Order.[4] The Applicant's chief compliance officer will document the frequency and results of such monitoring and testing, and the Applicant will maintain and preserve such documentation in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2016–29299 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[4] *See* Report of the Securities and Exchange Commission, Investment Trusts and Investment Companies, H.R. Doc. No. 279, 76th Cong., 2d Sess., pt. 3, at 2581, 2589 (1939); Hearings on S.3580 Before a Subcommittee of the Commission on Banking and Currency, 76th Cong., 3d Sess. 209, 212–23 (1940); Hearings on S. 3580 Before the Subcomm. of the Comm. on Banking and Currency, 76th Cong., 3d Sess. 322 (1940).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79436; File No. SR–BatsEDGA–2016–29]

Self-Regulatory Organizations; Bats EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Non-Substantive Changes to the Fee Schedule

December 1, 2016.

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 November 18, 2016, Bats EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange filed a proposal to make several non-substantive changes to the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to Exchange Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make certain clarifying and non-substantive changes to its fee schedule in order to improve formatting, eliminate certain redundancies, increase overall readability, and provide users with straightforward descriptions to augment overall comprehensibility and usability of the existing fee schedule. The Exchange notes that these changes are purely clerical and do not substantively amend any fee or rebate, nor do they alter the manner in which the Exchange assesses fees or calculates rebates. The proposed changes are simply intended to provide greater transparency to market participants regarding how the Exchange assesses fees and calculates rebates. Specifically, the Exchange proposes to:

- Capitalize the title of the column setting forth each tier's rate under footnotes 3 and 4;
- replace the phrase ''of at least'' with ''≥'' in all required criteria cells under footnotes 3 and 4;
- amend the description of the required criteria of ''Step-Up Tier 1'' and the ''Step-Up Tier 2'' under footnote 4 to begin with ''MPID adds/has'' and delete the phrase ''[o]n an MPID Basis''. Amending this description is intended to harmonize the format of the tier's criteria with that of other tier's listed under footnotes 3 and 4 which state ''Member has'' or ''Member adds''.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[6] Specifically, the Exchange believes that the proposed rule change is consistent with Sections 6(b)(4) of the Act of the Act [sic],[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange believes that the proposed changes are reasonable and equitable because they are intended to simplify the Exchange's fee schedule and provide greater transparency to market participants regarding how the Exchange assesses fees and calculates rebates. The Exchange notes that these changes are purely clerical and do not substantively amend any fee or rebate, nor do they alter the manner in which the Exchange assesses fees or calculates rebates. The Exchange also believes that the proposal is non-discriminatory because it applies uniformly to all Members. Finally, the Exchange believes that the proposed changes will make the fee schedule clearer and eliminate potential investor confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

system, and, in general, protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. To the contrary, the Exchange believes that the [sic] will not impose any burden on competition as the changes are purely clerical and do not amend and [sic] fee or rebate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and paragraph (f) of Rule 19b–4 thereunder.[9] 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–BatsEDGA–2016–29 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–BatsEDGA–2016–29. 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 Web site (*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 Web site 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 the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsEDGA–2016–29, and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29283 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79448; File No. SR–BX–2014–048]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Order Granting an Extension to Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Price Improvement Program Until December 1, 2017

December 1, 2016.

On November 28, 2014, the Commission issued an order pursuant to its authority under Rule 612(c) of Regulation NMS [1] (''Sub-Penny Rule'') that granted the NASDAQ BX, Inc. (''BX'' or ''Exchange'') a limited exemption from the Sub-Penny Rule in connection with the operation of the Exchange's Retail Price Improvement Program (''RPI Program'').[2] The limited exemption was granted concurrently with the Commission's approval of the Exchange's proposal to adopt the RPI Program on a one-year pilot term.[3] On November 20, 2015, the Commission extended the temporary exemption until December 2016 concurrently with an immediately effective filing that extended the operation of the RPI Program until December 1, 2016.[4]

The Exchange now seeks to extend the exemption until December 1, 2017.[5] The Exchange's request was made in conjunction with an immediately effective filing that extends the operation of the RPI Program until December 1, 2017.[6] In its request to extend the exemption, the Exchange notes that given the gradual implementation of the RPI Program and the preliminary participation and results, extending the exemption would provide additional opportunities for greater participation and assessment of the results. Accordingly, the Exchange has asked for additional time to allow it and the Commission to analyze data concerning the RPI Program that the Exchange has committed to provide to the Commission.[7]

For this reason and the reasons stated in the RPI Approval Order originally granting the limited exemption, the Commission, pursuant to its authority under Rule 612(c) of Regulation NMS, finds that extending the exemption is appropriate in the public interest and consistent with the protection of investors.

Therefore, it is hereby ordered that, pursuant to Rule 612(c) of Regulation NMS, the Exchange is granted an extension of the limited exemption from Rule 612 of Regulation NMS that allows the Exchange to accept and rank orders priced equal to or greater than $1.00 per share in increments of $0.001, in connection with the operation of its RPI Program, until December 1, 2017.

[1] 17 CFR 242.612(c).

[2] *See* Securities Exchange Act Release No. 73702, 79 FR 72049 (December 4, 2014), (SR–BX–2014–048) (''RPI Approval Order'').

[3] *See id.*

[4] *See* Securities Exchange Act Release No. 76495, 80 FR 74185 (November 27, 2015), (SR–BX–2014–048).

[5] *See* SR–BX–2016–065; *see also* Letter from Jeffrey Davis, Vice President and Deputy General Counsel and Secretary, NASDAQ BX, Inc. to Brent J. Fields, Secretary, and Securities and Exchange Commission, dated November 22, 2016 (''BX Letter'').

[6] *See* SR–BX–2016–065.

[7] *See e.g.,* BX Letter; SR–BX–2016–065; RPI Approval Order, *supra* note 2.

The limited and temporary exemption extended by this Order is subject to modification or revocation if at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Act. Responsibility for compliance with any applicable provisions of the Federal securities laws must rest with the persons relying on the exemption that are the subject of this Order.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29293 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79439; File No. SR–ICC–2016–014]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change To Provide for the Clearance of Additional Credit Default Swap Contracts

December 1, 2016.

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 November 18, 2016, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. 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 principal purpose of the proposed rule change is to revise the ICC Rulebook (the ''Rules'') to provide for the clearance of Standard Australian Corporate Single Name CDS contracts (collectively, ''STAC Contracts'') and Standard Australian Financial Corporate Single Name CDS contracts (collectively, ''STAFC Contracts'').

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC 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. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to adopt rules that will provide the basis for ICC to clear additional credit default swap contracts. Specifically, ICC proposes amending Chapter 26 of the ICC Rules to add Subchapters 26M and 26N to provide for the clearance of STAC and STAFC Contracts, respectively. ICC believes the addition of these contracts will benefit the market for credit default swaps by providing market participants the benefits of clearing, including reduction in counterparty risk and safeguarding of margin assets pursuant to clearing house rules. Clearing of the additional STAC and STAFC Contracts 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'').

STAC Contracts have similar terms to the Standard European Corporate Single Name CDS contracts (''STEC Contracts'') currently cleared by ICC and governed by Subchapter 26G of the ICC Rules. Accordingly, the proposed rules found in Subchapter 26M largely mirror the ICC Rules for STEC Contracts in Subchapter 26G, with certain modifications that reflect differences in terms and market conventions between those contracts and STAC Contracts. STAC Contracts will be denominated in United States Dollars.

ICC Rule 26M–102 (Definitions) sets forth the definitions used for the STAC Contracts. The definitions are substantially the same as the definitions found in Subchapter 26G of the ICC Rules, other than certain conforming changes. ICC Rules 26M–203 (Restriction on Activity), 26M–206 (Notices Required of Participants with respect to STAC Contracts), 26M–303 (STAC Contract Adjustments), 26M–309 (Acceptance of STAC Contracts by ICE Clear Credit), 26M–315 (Terms of the Cleared STAC Contract), 26M–316 (Relevant Physical Settlement Matrix Updates), 26M–502 (Specified Actions), and 26M–616 (Contract Modification) reflect or incorporate the basic contract specifications for STAC Contracts and are substantially the same as under Subchapter 26G of the ICC Rules.

STAFC Contracts have similar terms to the Standard European Financial Corporate Single Name CDS contracts (''STEFC Contracts'') currently cleared by ICC and governed by Subchapter 26H of the ICC Rules. Accordingly, the proposed rules found in Subchapter 26N largely mirror the ICC Rules for STEFC Contracts in Subchapter 26H, with certain modifications that reflect differences in terms and market conventions between those contracts and STAFC Contracts. STAFC Contracts will be denominated in United States Dollars.

ICC Rule 26N–102 (Definitions) sets forth the definitions used for the STAFC Contracts. The definitions are substantially the same as the definitions found in Subchapter 26H of the ICC Rules, other than certain conforming changes. ICC Rules 26N–203 (Restriction on Activity), 26N–206 (Notices Required of Participants with respect to STAFC Contracts), 26N–303 (STAFC Contract Adjustments), 26N–309 (Acceptance of STAFC Contracts by ICE Clear Credit), 26N–315 (Terms of the Cleared STAFC Contract), 26N–316 (Relevant Physical Settlement Matrix Updates), 26N–502 (Specified Actions), and 26N–616 (Contract Modification) reflect or incorporate the basic contract specifications for STAFC Contracts and are substantially the same as under Subchapter 26H of the ICC Rules.

Section 17A(b)(3)(F) of the Act[3] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions and to comply with the provisions of the Act and the rules and regulations thereunder. The STAC and STAFC Contracts proposed for clearing are similar to the STEC and STEFC Contracts currently cleared by ICC, and will be cleared pursuant to ICC's existing clearing arrangements and related financial safeguards, protections and risk management procedures. Clearing of the STAC and STAFC Contracts will allow market participants an increased ability to manage risk and ensure the safeguarding of margin assets

[8] 17 CFR 200.30–3(a)(83).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78q–1(b)(3)(F).

pursuant to clearing house rules. ICC believes that acceptance of the STAC and STAFC Contracts, on the terms and conditions set out in the Rules, is consistent with the prompt and accurate clearance of 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.[4]

Clearing of the STAC and STAFC Contracts will also satisfy the requirements of Rule 17Ad–22.[5] In particular, in terms of financial resources, ICC will apply its existing initial margin methodology to the additional contracts. ICC believes that this model will provide sufficient initial margin requirements to cover its credit exposure to its clearing members from clearing such contracts, consistent with the requirements of Rule 17Ad–22(b)(2).[6] In addition, ICC believes its Guaranty Fund, under its existing methodology, will, together with the required initial margin, provide sufficient financial resources to support the clearing of the additional contracts consistent with the requirements of Rule 17Ad–22(b)(3).[7] ICC also believes that its existing operational and managerial resources will be sufficient for clearing of the additional contracts, consistent with the requirements of Rule 17Ad–22(d)(4),[8] as the new contracts are substantially the same from an operational perspective as existing contracts. Similarly, ICC will use its existing settlement procedures and account structures for the new contracts, consistent with the requirements of Rule 17Ad–22(d)(5), (12) and (15)[9] as to the finality and accuracy of its daily settlement process and avoidance of the risk to ICC of settlement failures. ICC determined to accept the STAC and STAFC Contracts for clearing in accordance with its governance process, which included review of the contracts and related risk management considerations by the ICC Risk Committee and approval by its Board. These governance arrangements are consistent with the requirements of Rule 17Ad–22(d)(8).[10] Finally, ICC will apply its existing default management policies and procedures for the STAC and STAFC Contracts. ICC believes that these procedures allow for it to take timely action to contain losses and liquidity pressures and to continue meeting its obligations in the event of clearing member insolvencies or defaults in respect of the additional single names, in accordance with Rule 17Ad–22(d)(11).[11]

(B) Self-Regulatory Organization's Statement on Burden on Competition

The STAC and STAFC Contracts will be available to all ICC participants for clearing. The clearing of these STAC and STAFC Contracts by ICC does not preclude the offering of the STAC and STAFC Contracts for clearing by other market participants. Accordingly, ICC does not believe that clearance of the STAC and STAFC Contracts will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2016–014 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–ICC–2016–014. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's Web site at *https://www.theice.com/clear-credit/regulation.*

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2016–014 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29285 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[4] 15 U.S.C. 78q–1(b)(3)(F).

[5] 17 CFR 240.17Ad–22.

[6] 17 CFR 240.17Ad–22(b)(2).

[7] 17 CFR 240.17Ad–22(b)(3).

[8] 17 CFR 240.17Ad–22(d)(4).

[9] 17 CFR 240.17Ad–22(d)(5), (12) and (15).

[10] 17 CFR 240.17Ad–22(d)(8).

[11] 17 CFR 240.17Ad–22(d)(11).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79442; File No. SR–CBOE–2016–083]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Penny Pilot Program

December 1, 2016.

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 November 23, 2016, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the operation of Penny Pilot Program through June 30, 2017. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 6.42. Minimum Increments for Bids and Offers

The Board of Directors may establish minimum increments for options traded on the Exchange. When the Board of Directors determines to change the minimum increments, the Exchange will designate such change as a stated policy, practice, or interpretation with respect to the administration of Rule 6.42 within the meaning of subparagraph (3)(A) of subsection 19(b) of the Exchange Act and will file a rule change for effectiveness upon filing with the Commission. Until such time as the Board of Directors makes a change to the minimum increments, the following minimum increments shall apply to options traded on the Exchange:

(1) No change.

(2) No change.

(3) The decimal increments for bids and offers for all series of the option classes participating in the Penny Pilot Program are: $0.01 for all option series quoted below $3 (including LEAPS), and $0.05 for all option series $3 and above (including LEAPS). For QQQQs, IWM, and SPY, the minimum increment is $0.01 for all option series. The Exchange may replace any option class participating in the Penny Pilot Program that has been delisted with the next most actively-traded, multiply-listed option class, based on national average daily volume in the preceding six calendar months, that is not yet included in the Pilot Program. Any replacement class would be added on the second trading day following [July 1, 2016]*January 1, 2017.* The Penny Pilot shall expire on [December 31, 2016]*June 30, 2017.*

(4) No change.

. . . Interpretations and Policies:

.01–.04 No change.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*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 Penny Pilot Program (the ''Pilot Program'') is scheduled to expire on December 31, 2016. CBOE proposes to extend the Pilot Program until June 30, 2017. CBOE believes that extending the Pilot Program will allow for further analysis of the Pilot Program and a determination of how the Pilot Program should be structured in the future.

During this extension of the Pilot Program, CBOE proposes that it may replace any option class that is currently included in the Pilot Program and that has been delisted with the next most actively traded, multiply listed option class that is not yet participating in the Pilot Program (''replacement class''). Any replacement class would be determined based on national average daily volume in the preceding six months,[5] and would be added on the second trading day following January 1, 2017. CBOE will employ the same parameters to prospective replacement classes as approved and applicable in determining the existing classes in the Pilot Program, including excluding high-priced underlying securities.[6] CBOE will announce to its Trading Permit Holders by circular any replacement classes in the Pilot Program.

CBOE is specifically authorized to act jointly with the other options exchanges participating in the Pilot Program in identifying any replacement class.

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.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In particular, the proposed rule change allows for an extension of the Pilot Program for the benefit of market participants.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The month immediately preceding a replacement class's addition to the Pilot Program (*i.e.,* December) would not be used for purposes of the six-month analysis. Thus, a replacement class to be added on the second trading day following January 1, 2017 would be identified based on The Option Clearing Corporation's trading volume data from June 1, 2016 through November 30, 2016.

[6] *See* Securities Exchange Act Release No. 60864 (October 22, 2009), 74 FR 55876 (October 29, 2009) (SR–CBOE–2009–76).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Pilot Program, the proposed rule change will allow for further analysis of the Pilot Program and a determination of how the Program shall be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. In addition, the Exchange has been authorized to act jointly in extending the Pilot Program and believes the other exchanges will be filing similar extensions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) [11] thereunder. Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov. Please include File Number* SR–CBOE–2016–083 *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–2016–083. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–083 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29287 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IA–4578; File No. 803–00236]

Merrill Lynch, Pierce, Fenner & Smith Incorporated; Notice of Application

December 1, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an exemptive order under section 206A of the Investment Advisers Act of 1940 (''Advisers Act'') providing an exemption from the written disclosure and consent requirements of section 206(3).

Applicant: Merrill Lynch, Pierce, Fenner & Smith Incorporated (''Applicant'').

Relevant Advisers Act Sections: Exemption requested under section 206A from the written disclosure and consent requirements of section 206(3).

Summary of Application: Applicant requests that the Commission issue an order under section 206A exempting it and Future Advisers (as defined below) from the written disclosure and consent requirements of section 206(3) with respect to principal transactions with nondiscretionary advisory client accounts.

Filing Dates: The application was filed on November 23, 2016.

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 December 27, 2016, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Advisers Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicant, Mackenzie E. Crane, Esq., Bank of America, 100 Federal Street, MA5–100–03–09, Boston, MA 02110 or James E. Anderson, Esq. and Kimberly B. Saunders, Esq., Willkie Farr & Gallagher LLP, 1875 K Street NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Robert Shapiro, Senior Counsel, at (202) 551–7758 (Chief Counsel's Office, Division of Investment Management) or Melissa Harke, Senior Special Counsel, at (202) 551–6787 (Investment Adviser Regulation Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site at *http://www.sec.gov/rules/iareleases.shtml* or by calling (202) 551–8090.

Applicant seeks relief from the written disclosure and consent requirements of section 206(3) of the Advisers Act that would be similar to relief currently provided by Advisers Act rule 206(3)–3T (the ''Rule''), which will expire by its terms on December 31, 2016. The relief sought by Applicant, if granted, would be subject to conditions similar to those under the Rule, as well as certain revised or additional conditions.

Applicant's Representations

1. The Applicant is registered as an investment adviser with the Commission and is a registered broker-dealer. The Applicant is a subsidiary of Bank of America Corporation, a diversified financial services company with operations around the world. The Applicant offers a number of advisory programs, including Merrill Lynch Personal Advisor (''MLPA''), a nondiscretionary advisory program, and Merrill Lynch Investment Advisory Program (''MLIAP''). While the Applicant offers both discretionary and nondiscretionary advisory services under MLIAP, the relief sought by the Applicant, as it relates to MLIAP, is limited to the client accounts enrolled in nondiscretionary strategies.

2. In 2007, many of the Applicant's fee-based brokerage accounts were converted to nondiscretionary advisory accounts in MLPA, following the invalidation of former rule 202(a)(11)–1 under the Advisers Act. When these accounts had been fee-based brokerage accounts, the Applicant, in its capacity as a broker-dealer, engaged in principal transactions with its customers, in accordance with applicable law. The Applicant currently relies on the Rule to engage in principal transactions with its client accounts in MLPA and client accounts enrolled in nondiscretionary strategies in MLIAP.

3. The Applicant currently has approximately 393,535 client accounts enrolled in nondiscretionary strategies in MLIAP. Those accounts have approximately $157 billion in assets under management as of June 30, 2016. In the period January 1, 2015 through December 31, 2015, there were approximately 53.9 million trades in MLIAP, involving approximately $79.1 billion in securities. In the period January 1, 2015 through December 31, 2015, 25,114 trades were effected in reliance on the Rule in 5,978 unique accounts, representing an approximate average of 4.2 such trades per account. Approximately 70 percent of the trades done in reliance on the Rule in this period were purchases by client accounts; the average purchase was approximately $55,850. Approximately 30 percent of the trades done in reliance on the Rule in this period were sales from client accounts; the average sale was approximately $41,504.

4. In 2013, the Applicant began transitioning its investment advisory client accounts from five legacy investment advisory programs, including MLPA, to MLIAP. The Applicant currently has approximately 3,239 client accounts remaining in MLPA. Those accounts have approximately $5.5 billion in assets under management as of June 30, 2016. It is expected that these client accounts will either transition to MLIAP or terminate their investment advisory relationship with the Applicant, at which point MLPA will be retired. In the period January 1, 2015 through December 31, 2015, there were approximately 675,000 trades in MLPA, involving approximately $13 billion in securities. In the period January 1, 2015 through December 31, 2015, 11,400 trades were effected in reliance on the Rule in 2,857 unique accounts, representing an approximate average of 4 such trades per account. Approximately 70 percent of the trades done in reliance on the Rule in this period were purchases by client accounts; the average purchase was approximately $77,600. Approximately 30 percent of the trades done in reliance on the Rule in this period were sales from client accounts; the average sale was approximately $77,517.

5. From January 1, 2015 to December 31, 2015, Applicant did not rely on the Rule for any principal trades in securities it underwrote. Any principal transactions in securities that are underwritten by the Applicant are effected in accordance with section 206(3) of the Advisers Act.

6. The Applicant acknowledges that the Order, if granted, would not be construed as relieving in any way the Applicant from acting in the best interests of an advisory client, including fulfilling the duty to seek the best execution for the particular transaction for the advisory client; nor shall it relieve the Applicant from any obligation that may be imposed by sections 206(1) or (2) of the Advisers Act or by other applicable provisions of the federal securities laws or applicable FINRA rules.

Applicant's Legal Analysis

1. Section 206(3) provides that it is unlawful for any investment adviser, directly or indirectly, acting as principal for its own account, knowingly to sell any security to or purchase any security from a client, without disclosing to the client in writing before the completion of the transaction the capacity in which the adviser is acting and obtaining the client's consent to the transaction. Rule 206(3)–3T deems an investment adviser to be in compliance with the provisions of section 206(3) of the Advisers Act when the investment adviser, or a person controlling, controlled by, or under common control with the investment adviser, acting as principal for its own account, sells to or purchases from an advisory client any security, provided that the investment adviser complies with the conditions of the Rule.

2. Rule 206(3)–3T requires, among other things, that the investment adviser obtain a client's written, revocable consent prospectively authorizing the adviser, directly or indirectly, acting as principal for its own account, to sell any security to or purchase any security from the client. The consent must be obtained after the adviser provides the client with written disclosure about: (i) The circumstances under which the investment adviser may engage in principal transactions with the client; (ii) the nature and significance of the conflicts the investment adviser has with its client's interests as a result of those transactions; and (iii) how the investment adviser addresses those conflicts. The investment adviser also must provide trade-by-trade disclosure to the client, before the execution of each principal transaction, of the capacity in which the adviser may act with respect to the transaction, and obtain the client's consent (which may be written or oral) to the transaction. The Rule is available only to an

investment adviser that is also a broker-dealer registered under section 15 of the Securities Exchange Act of 1934 (''Exchange Act'') and may only be relied upon with respect to a nondiscretionary account that is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member. Rule 206(3)–3T is not available for principal transactions if the investment adviser or a person who controls, is controlled by, or is under common control with the adviser (''control person'') is the issuer or is an underwriter of the security, except that an adviser may rely on the Rule for trades in which the adviser or a control person is an underwriter of non-convertible investment-grade debt securities.

3. The investment adviser also must provide to the client a trade confirmation that, in addition to the requirements of rule 10b–10 under the Exchange Act, includes a conspicuous, plain English statement informing the client that the investment adviser disclosed to the client before the execution of the transaction that the investment adviser may act as principal in connection with the transaction, that the client authorized the transaction, and that the investment adviser sold the security to or bought the security from the client for its own account. The investment adviser also must deliver to the client, at least annually, a written statement listing all transactions that were executed in the account in reliance on the Rule, including the date and price of each transaction.

4. Rule 206(3)–3T is scheduled to expire on December 31, 2016. Upon expiration, the Applicant would be required to provide trade-by-trade written disclosure to each nondiscretionary advisory client with whom the Applicant sought to engage in a principal transaction in accordance with section 206(3). The Applicant submits that its nondiscretionary clients, through the Applicant's current reliance on the Rule, have had access to the Applicant's inventory through principal transactions for a number of years, and expect to continue to have such access in the future. The Applicant believes that engaging in principal transactions with its clients provides certain benefits to its clients, including access to securities of limited availability, such as municipal bonds, and that the written disclosure requirement of section 206(3) acts as an operational barrier to its ability to engage in principal trades with its clients, especially when the transaction involves securities of limited availability.

5. Unless the Applicant is provided an exemption from the written disclosure and client consent requirements of section 206(3), Applicant believes that it will be unable to provide the same range of services and access to the same types of securities to its nondiscretionary advisory clients as it currently is able to provide to clients under the Rule.

6. The Applicant notes that, if the requested relief is granted, it will remain subject to the fiduciary duties that are generally enforceable under sections 206(1) and 206(2) of the Advisers Act, which, in general terms, require the Applicant to: (i) Disclose material facts about the advisory relationship to its clients; (ii) treat each client fairly; and (iii) act only in the best interests of its client, disclosing conflicts of interest when present and obtaining client consent to arrangements that present such conflicts.

7. The Applicant further notes that, in its capacity as a broker-dealer with respect to these accounts, it will remain subject to a comprehensive set of Commission and FINRA regulations that apply to the relationship between a broker-dealer and its customer in addition to the fiduciary duties an adviser owes a client. These rules require, among other things, that the Applicant deal fairly with its customers, seek to obtain best execution of customer orders, and make only suitable recommendations. These obligations are designed to promote business conduct that protects customers from abusive practices that may not necessarily be fraudulent, and to protect against unfair prices and excessive commissions. Specifically, these provisions, among other things, require that the prices charged by the Applicant be reasonably related to the prevailing market, and limit the commissions and mark-ups the Applicant can charge. Additionally, these obligations require that the Applicant have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer, based on information obtained through reasonable diligence.

8. The Applicant requests that the Commission issue an Order pursuant to section 206A exempting it from the written disclosure and consent requirements of section 206(3) only with respect to client accounts in MLPA, nondiscretionary strategies in MLIAP, and any similar nondiscretionary program to be created in the future. The Applicant also requests that the Commission's Order apply to future investment advisers controlling, controlled by, or under common control with the Applicant (''Future Advisers''). Any Future Adviser relying on any Order granted pursuant to the application will comply with the terms and conditions stated in the application.[1]

Applicant's Conditions

The Applicant agrees that any Order granting the requested relief will be subject to the following conditions:

1. The investment adviser will exercise no ''investment discretion'' (as such term is defined in section 3(a)(35) of the Exchange Act), except investment discretion granted by the advisory client on a temporary or limited basis,[2] with respect to the client's account.

2. The investment adviser will not trade in reliance on this Order any security for which the investment adviser or any person controlling, controlled by, or under common control with the investment adviser is the issuer, or, at the time of the sale, an underwriter (as defined in section 202(a)(20) of the Advisers Act).

3. The investment adviser will not directly or indirectly require the client to consent to principal trading as a condition to opening or maintaining an account with the investment adviser.

4. The advisory client has executed a written revocable consent prospectively authorizing the investment adviser directly or indirectly to act as principal for its own account in selling any security to or purchasing any security from the advisory client. The advisory client's written consent must be obtained through a signature or other positive manifestation of consent that is separate from or in addition to the signature indicating the client's consent to the advisory agreement. The separate

[1] All entities that currently intend to rely on any order granted pursuant to the application are named as Applicants.

[2] Discretion is considered to be temporary or limited for purposes of this condition when the investment adviser is given discretion: (i) As to the price at which or the time to execute an order given by a client for the purchase or sale of a definite amount or quantity of a specified security; (ii) on an isolated or infrequent basis, to purchase or sell a security or type of security when a client is unavailable for a limited period of time not to exceed a few months; (iii) as to cash management, such as to exchange a position in a money market fund for another money market fund or cash equivalent; (iv) to purchase or sell securities to satisfy margin requirements; (v) to sell specific bonds and purchase similar bonds in order to permit a client to take a tax loss on the original position; (vi) to purchase a bond with a specified credit rating and maturity; and (vii) to purchase or sell a security or type of security limited by specific parameters established by the client. *See, e.g., Temporary Rule Regarding Principal Trades with Certain Advisory Clients,* Investment Advisers Act Release No. 2653 (Sept. 24, 2007) at n. 31.

or additional signature line or alternative means of expressing consent must be preceded immediately by prominent, plain English disclosure containing either: (a) An explanation of: (i) The circumstances under which the investment adviser directly or indirectly may engage in principal transactions; (ii) the nature and significance of conflicts with its client's interests as a result of the transactions; and (iii) how the investment adviser addresses those conflicts; or (b) a statement explaining that the client is consenting to principal transactions, followed by a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific page or pages on which such disclosure is located; provided, however, that if the investment adviser requires time to modify its electronic systems to provide the disclosure in (a)(i)–(iii) above immediately preceding the separate or additional signature line, the investment adviser may, while updating such electronic systems, and for no more than 90 days from the date of the Order, instead provide a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific section in such document in which such disclosure is located. *Transition provision:* To the extent that the adviser obtained fully informed written revocable consent from an advisory client for purposes of rule 206(3)–3T(a)(3) prior to the date of this Order, the adviser may rely on this Order with respect to such client without obtaining additional prospective consent from such client.

5. The investment adviser, prior to the execution of each transaction in reliance on this Order, will: (a) Inform the advisory client, orally or in writing, of the capacity in which it may act with respect to such transaction; and (b) obtain consent from the advisory client, orally or in writing, to act as principal for its own account with respect to such transaction.

6. The investment adviser will send a written confirmation at or before completion of each such transaction that includes, in addition to the information required by rule 10b–10 under the Exchange Act, a conspicuous, plain English statement informing the advisory client that the investment adviser: (a) Disclosed to the client prior to the execution of the transaction that the adviser may be acting in a principal capacity in connection with the transaction and the client authorized the transaction; and (b) sold the security to, or bought the security from, the client for its own account.

7. The investment adviser will send to the client, no less frequently than annually, written disclosure containing a list of all transactions that were executed in the client's account in reliance upon this Order, and the date and price of each such transaction.

8. The investment adviser is a broker-dealer registered under section 15 of the Exchange Act and each account for which the investment adviser relies on this Order is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member.

9. Each written disclosure required as a condition to this Order will include a conspicuous, plain English statement that the client may revoke the written consent referred to in Condition 4 above without penalty at any time by written notice to the investment adviser in accordance with reasonable procedures established by the investment adviser, but in all cases such revocation must be given effect within 5 business days of the investment adviser's receipt thereof.

10. The investment adviser will maintain records sufficient to enable verification of compliance with the conditions of this Order. Such records will include, *without limitation:* (a) Documentation sufficient to demonstrate compliance with each disclosure and consent requirement under this Order; (b) in particular, documentation sufficient to demonstrate that, prior to the execution of each transaction in reliance on this Order, the adviser informed the advisory client of the capacity in which it may act with respect to the transaction and that it received the advisory client's consent (if the investment adviser informs the client orally of the capacity in which it may act with respect to such transaction or obtains oral consent, such records may, for example, include recordings of telephone conversations or contemporaneous written notations); and (c) documentation sufficient to enable assessment of compliance by the investment adviser with sections 206(1) and (2) of the Advisers Act in connection with its reliance on this Order.[3] In each case, such records will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the investment adviser, and be available for inspection by the staff of the Commission.

11. The investment adviser will adopt written compliance policies and procedures reasonably designed to ensure, and the investment adviser's chief compliance officer will monitor, the investment adviser's compliance with the conditions of this Order. The investment adviser's chief compliance officer will, on at least a quarterly basis, conduct testing reasonably sufficient to verify such compliance. Such written policies and procedures, monitoring and testing will address, *without limitation:* (a) Compliance by the investment adviser with its disclosure and consent requirements under this Order; (b) the integrity and operation of electronic systems employed by the investment adviser in connection with its reliance on this Order; (c) compliance by the investment adviser with its recordkeeping obligations under this Order; and (d) whether there is any evidence of the investment adviser engaging in ''dumping'' in connection with its reliance on this Order.[4] The investment adviser's chief compliance officer will document the frequency and results of such monitoring and testing, and the investment adviser will maintain and preserve such documentation in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the investment adviser, and be available for inspection by the staff of the Commission.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2016–29297 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[3] For example, under sections 206(1) and (2), an adviser may not engage in any transaction on a principal basis with a client that is not consistent with the best interests of the client or that subrogates the client's interests to the adviser's own. *Cf.* Investment Advisers Act Release No. 2106 (Jan. 31, 2003) (adopting Rule 206(4)–6).

[4] *See* Report of the Securities and Exchange Commission, Investment Trusts and Investment Companies, H.R. Doc. No. 279, 76th Cong., 2d Sess., pt. 3, at 2581, 2589 (1939); Hearings on S. 3580 Before a Subcommittee of the Commission on Banking and Currency, 76th Cong., 3d Sess. 209, 212–23 (1940); Hearings on S. 3580 Before the Subcomm. of the Comm. on Banking and Currency, 76th Cong., 3d Sess. 322 (1940).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IA–4581; File No. 803–00234]

Wells Fargo Advisors, LLC and Wells Fargo Advisors Financial Network, LLC; Notice of Application

December 1, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an exemptive order under section 206A of the Investment Advisers Act of 1940

(''Advisers Act'') providing an exemption from the written disclosure and consent requirements of section 206(3).

Applicants: Wells Fargo Advisors, LLC (''WFA'') and Wells Fargo Advisors Financial Network, LLC (''FiNet,'' and, together with WFA, ''Applicants'').

Relevant Advisers Act Sections: Exemption requested under section 206A from the written disclosure and consent requirements of section 206(3).

Summary of Application: Applicants request that the Commission issue an order under section 206A exempting them and Future Advisers (as defined below) from the written disclosure and consent requirements of section 206(3) with respect to principal transactions with nondiscretionary advisory client accounts.

Filing Dates: The application was filed on November 22, 2016.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 27, 2016, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Advisers Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, Laura E. Flores and Steven W. Stone, Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Ave. NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Robert Shapiro, Senior Counsel, at (202) 551–7758 (Chief Counsel's Office, Division of Investment Management) or Melissa Harke, Senior Special Counsel, at (202) 551–6787 (Investment Adviser Regulation Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site at *http://www.sec.gov/rules/iareleases.shtml* or by calling (202) 551–8090.

Applicants seek relief from the written disclosure and consent requirements of section 206(3) of the Advisers Act that would be similar to relief currently provided by Advisers Act rule 206(3)-3T (the ''Rule''), which will expire by its terms on December 31, 2016. The relief sought by Applicants, if granted, would be subject to conditions similar to those under the Rule, as well as certain revised or additional conditions.

Applicants' Representations

1. WFA and FiNet are each registered as investment advisers with the Commission and each is a registered broker-dealer. WFA and FiNet are each indirect subsidiaries and under the common control of Wells Fargo & Company, a diversified financial services company with operations around the world. Each of WFA and FiNet offers a number of advisory programs, including Asset Advisor (the ''Program''), a nondiscretionary advisory program.

2. WFA created the Program in 2004; FiNet has been offering the Program since 2004. In September 2007, a number of WFA's and FiNet's fee-based brokerage accounts were converted to nondiscretionary advisory accounts in the Program following the invalidation of former Rule 202(a)(11)–1 under the Advisers Act. When these accounts had been fee-based brokerage accounts, the Applicants, in their capacity as broker-dealers, engaged in principal transactions with their respective customers in accordance with applicable law. The Applicants currently rely on the Rule to engage in principal transactions with their client accounts in the Program.

3. The Applicants currently have more than 260,000 client accounts enrolled in the Program. Those accounts have approximately $115 billion in assets under management as of August 30, 2016. For 2014 and 2015, WFA and FiNet conducted 27,478 and 2,476 principal trades, respectively, in reliance on the Rule, involving more than $1.5 billion and $141 million in securities, respectively. Approximately 78% percent of the trades done in reliance on the Rule in 2015 were purchases by client accounts; the average purchase was approximately $43,000. Approximately 22% percent of the trades done in reliance on the Rule in 2015 were sales from client accounts; the average sale was approximately $36,000.

4. Any principal transactions in securities that are underwritten by Applicants or an affiliate are effected in accordance with section 206(3) of the Advisers Act.

5. The Applicants acknowledge that the Order, if granted, would not be construed as relieving in any way the Applicants from acting in the best interests of an advisory client, including fulfilling the duty to seek the best execution for the particular transaction for the advisory client; nor shall it relieve the Applicants from any obligation that may be imposed by sections 206(1) or (2) of the Advisers Act or by other applicable provisions of the federal securities laws or applicable FINRA rules.

Applicants' Legal Analysis

1. Section 206(3) provides that it is unlawful for any investment adviser, directly or indirectly, acting as principal for its own account, knowingly to sell any security to or purchase any security from a client, without disclosing to the client in writing before the completion of the transaction the capacity in which the adviser is acting and obtaining the client's consent to the transaction. Rule 206(3)–3T deems an investment adviser to be in compliance with the provisions of section 206(3) of the Advisers Act when the investment adviser, or a person controlling, controlled by, or under common control with the investment adviser, acting as principal for its own account, sells to or purchases from an advisory client any security, provided that the investment adviser complies with the conditions of the Rule.

2. Rule 206(3)–3T requires, among other things, that the investment adviser obtain a client's written, revocable consent prospectively authorizing the adviser, directly or indirectly, acting as principal for its own account, to sell any security to or purchase any security from the client. The consent must be obtained after the adviser provides the client with written disclosure about: (i) The circumstances under which the investment adviser may engage in principal transactions with the client; (ii) the nature and significance of the conflicts the investment adviser has with its client's interests as a result of those transactions; and (iii) how the investment adviser addresses those conflicts. The investment adviser also must provide trade-by-trade disclosure to the client, before the execution of each principal transaction, of the capacity in which the adviser may act with respect to the transaction, and obtain the client's consent (which may be written or oral) to the transaction. The Rule is available only to an investment adviser that is also a broker-dealer registered under section 15 of the

Securities Exchange Act of 1934 (''Exchange Act'') and may only be relied upon with respect to a nondiscretionary account that is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member. Rule 206(3)–3T is not available for principal transactions if the investment adviser or a person who controls, is controlled by, or is under common control with the adviser (''control person'') is the issuer or is an underwriter of the security, except that an adviser may rely on the Rule for trades in which the adviser or a control person is an underwriter of non-convertible investment-grade debt securities.

3. The investment adviser also must provide to the client a trade confirmation that, in addition to the requirements of rule 10b–10 under the Exchange Act, includes a conspicuous, plain English statement informing the client that the investment adviser disclosed to the client before the execution of the transaction that the investment adviser may act as principal in connection with the transaction, that the client authorized the transaction, and that the investment adviser sold the security to or bought the security from the client for its own account. The investment adviser also must deliver to the client, at least annually, a written statement listing all transactions that were executed in the account in reliance on the Rule, including the date and price of each transaction.

4. Rule 206(3)–3T is scheduled to expire on December 31, 2016. Upon expiration, the Applicants would be required to provide trade-by-trade written disclosure to each nondiscretionary advisory client with whom the Applicants sought to engage in a principal transaction in accordance with section 206(3). The Applicants submit that their nondiscretionary clients, through the Applicants' current reliance on the Rule, have had access to the Applicants' inventory through principal transactions for a number of years, and expect to continue to have such access in the future. The Applicants believe that engaging in principal transactions with their clients provides certain benefits to their clients, including access to securities of limited availability, such as municipal bonds, and that the written disclosure and client consent requirements of section 206(3) act as an operational barrier to their ability to engage in principal trades with their clients, especially when the transaction involves securities of limited availability.

5. Unless the Applicants are provided an exemption from the written disclosure and client consent requirements of section 206(3), Applicants believe that they will be unable to provide the same range of services and access to the same types of securities to their nondiscretionary advisory clients as they currently is able to provide to clients under the Rule.

6. The Applicants note that, if the requested relief is granted, they will remain subject to the fiduciary duties that are generally enforceable under sections 206(1) and 206(2) of the Advisers Act, which, in general terms, require the Applicants to: (i) Disclose material facts about the advisory relationship to their clients; (ii) treat each client fairly; and (iii) act only in the best interests of their client, disclosing conflicts of interest when present and obtaining client consent to arrangements that present such conflicts.

7. The Applicants further note that, in their capacity as broker-dealers with respect to these accounts, they will remain subject to a comprehensive set of Commission and FINRA regulations that apply to the relationship between a broker-dealer and its customer in addition to the fiduciary duties an adviser owes a client. These rules require, among other things, that the Applicants deal fairly with their customers, seek to obtain best execution of customer orders, and make only suitable recommendations. These obligations are designed to promote business conduct that protects customers from abusive practices that may not necessarily be fraudulent, and to protect against unfair prices and excessive commissions. Specifically, these provisions, among other things, require that the prices charged by the Applicants be reasonably related to the prevailing market, and limit the commissions and mark-ups the Applicants can charge. Additionally, these obligations require that the Applicants have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer, based on information obtained through reasonable diligence.

8. The Applicants request that the Commission issue an Order pursuant to section 206A exempting them from the written disclosure and consent requirements of section 206(3) only with respect to client accounts in the Program and any similar nondiscretionary program to be created in the future. The Applicants also request that the Commission's Order apply to future investment advisers controlling, controlled by, or under common control with the Applicants (''Future Advisers''). Any Future Adviser relying on any Order granted pursuant to the application will comply with the terms and conditions stated in the application.[1]

Applicants' Conditions

The Applicants agree that any Order granting the requested relief will be subject to the following conditions:

1. The Applicants will exercise no ''investment discretion'' (as such term is defined in section 3(a)(35) of the Exchange Act), except investment discretion granted by the advisory client on a temporary or limited basis[2], with respect to the client's account.

2. The Applicants will not trade in reliance on this Order any security for which either Applicant or any person controlling, controlled by, or under common control with the Applicants is the issuer, or, at the time of the sale, an underwriter (as defined in section 202(a)(20) of the Advisers Act).

3. The Applicants will not directly or indirectly require the client to consent to principal trading as a condition to opening or maintaining an account with an Applicant.

4. The advisory client has executed a written revocable consent prospectively authorizing the Applicants directly or indirectly to act as principal for their own account in selling any security to or purchasing any security from the advisory client. The advisory client's written consent must be obtained through a signature or other positive manifestation of consent that is separate from or in addition to the signature indicating the client's consent to the advisory agreement. The separate or additional signature line or alternative means of expressing consent must be

[1] All entities that currently intend to rely on any order granted pursuant to the application are named as Applicants.

[2] Discretion is considered to be temporary or limited for purposes of this condition when the investment adviser is given discretion: (i) As to the price at which or the time to execute an order given by a client for the purchase or sale of a definite amount or quantity of a specified security; (ii) on an isolated or infrequent basis, to purchase or sell a security or type of security when a client is unavailable for a limited period of time not to exceed a few months; (iii) as to cash management, such as to exchange a position in a money market fund for another money market fund or cash equivalent; (iv) to purchase or sell securities to satisfy margin requirements; (v) to sell specific bonds and purchase similar bonds in order to permit a client to take a tax loss on the original position; (vi) to purchase a bond with a specified credit rating and maturity; and (vii) to purchase or sell a security or type of security limited by specific parameters established by the client. *See, e.g., Temporary Rule Regarding Principal Trades with Certain Advisory Clients,* Investment Advisers Act Release No. 2653 (Sept. 24, 2007) at n. 31.

preceded immediately by prominent, plain English disclosure containing either: (a) An explanation of: (i) The circumstances under which an Applicant directly or indirectly may engage in principal transactions; (ii) the nature and significance of conflicts with its client's interests as a result of the transactions; and (iii) how an Applicant addresses those conflicts; or (b) a statement explaining that the client is consenting to principal transactions, followed by a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific page or pages on which such disclosure is located; provided, however, that if an Applicant requires time to modify its electronic systems to provide the specific page cross-reference required by clause (b), the Applicant may, while updating such electronic systems, and for no more than 90 days from the date of the Order, instead provide a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific section in such document in which such disclosure is located. *Transition provision:* To the extent that the Applicants obtained fully informed written revocable consent from an advisory client for purposes of rule 206(3)–3T(a)(3) prior to December 31, 2016, the Applicants may rely on this Order with respect to such client without obtaining additional prospective consent from such client.

5. The Applicants, prior to the execution of each transaction in reliance on this Order, will: (a) Inform the advisory client, orally or in writing, of the capacity in which they may act with respect to such transaction; and (b) obtain consent from the advisory client, orally or in writing, to act as principal for their own account with respect to such transaction.

6. The Applicants will send a written confirmation at or before completion of each such transaction that includes, in addition to the information required by rule 10b–10 under the Exchange Act, a conspicuous, plain English statement informing the advisory client that the Applicants: (a) Disclosed to the client prior to the execution of the transaction that the Applicants may be acting in a principal capacity in connection with the transaction and the client authorized the transaction; and (b) sold the security to, or bought the security from, the client for its own account.

7. The Applicants will send to the client, no less frequently than annually, written disclosure containing a list of all transactions that were executed in the client's account in reliance upon this Order, and the date and price of each such transaction.

8. Each Applicant is a broker-dealer registered under section 15 of the Exchange Act and each account for which the Applicants rely on this Order is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member.

9. Each written disclosure required as a condition to this Order will include a conspicuous, plain English statement that the client may revoke the written consent referred to in Condition 4 above without penalty at any time by written notice to the Applicants in accordance with reasonable procedures established by the Applicants, but in all cases such revocation must be given effect within 5 business days of the Applicants' receipt thereof.

10. The Applicants will maintain records sufficient to enable verification of compliance with the conditions of this Order. Such records will include, *without limitation:* (a) Documentation sufficient to demonstrate compliance with each disclosure and consent requirement under this Order; (b) in particular, documentation sufficient to demonstrate that, prior to the execution of each transaction in reliance on this Order, each Applicant informed the relevant advisory client of the capacity in which the Applicant may act with respect to the transaction and that it received the advisory client's consent (if the Applicant informs the client orally of the capacity in which it may act with respect to such transaction or obtains oral consent, such records may, for example, include recordings of telephone conversations or contemporaneous written notations); and (c) documentation sufficient to enable assessment of compliance by the Applicants with sections 206(1) and (2) of the Advisers Act in connection with its reliance on this Order.[3] In each case, such records will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicants, and be available for inspection by the staff of the Commission.

11. The Applicants will adopt written compliance policies and procedures reasonably designed to ensure, and each Applicant's chief compliance officer will monitor, the Applicant's compliance with the conditions of this Order. Each Applicant's chief compliance officer will, on at least a quarterly basis, conduct testing reasonably sufficient to verify such compliance. Such written policies and procedures, monitoring and testing will address, *without limitation:* (a) Compliance by the Applicant with its disclosure and consent requirements under this Order; (b) the integrity and operation of electronic systems employed by the Applicant in connection with its reliance on this Order; (c) compliance by the Applicant with its recordkeeping obligations under this Order; and (d) whether there is any evidence of the Applicant engaging in ''dumping'' in connection with its reliance on this Order.[4] Each Applicant's chief compliance officer will document the frequency and results of such monitoring and testing, and each Applicant will maintain and preserve such documentation in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2016–29300 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[3] For example, under sections 206(1) and (2), an adviser may not engage in any transaction on a principal basis with a client that is not consistent with the best interests of the client or that subrogates the client's interests to the adviser's own. *Cf.* Investment Advisers Act Release No. 2106 (Jan. 31, 2003) (adopting Rule 206(4)–6).

[4] *See* Report of the Securities and Exchange Commission, Investment Trusts and Investment Companies, H.R. Doc. No. 279, 76th Cong., 2d Sess., pt. 3, at 2581, 2589 (1939); Hearings on S. 3580 Before a Subcommittee of the Commission on Banking and Currency, 76th Cong., 3d Sess. 209, 212–23 (1940); Hearings on S. 3580 Before the Subcomm. of the Comm. on Banking and Currency, 76th Cong., 3d Sess. 322 (1940).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32375; 812–14685]

CWM Advisors, LLC, et al.; Notice of Application

December 1, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of

the Act. The requested order would permit (a) index-based series of certain open-end management investment companies (''Funds'') to issue shares redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value (''NAV''); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds (''Funds of Funds'') to acquire shares of the Funds.

Applicants: CWM Advisors, LLC (''CWM''), a California limited liability company registered as an investment adviser under the Investment Advisers Act of 1940 and Northern Lights Fund Trust IV (''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series.

Filing Dates: The application was filed on August 10, 2016.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 27, 2016 and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: CWM Advisors, LLC, 650 San Benito St, Ste. 130, Hollister, CA 95023; Northern Lights Fund Trust IV, 17605 Wright Street, Omaha, NE 68130.

FOR FURTHER INFORMATION CONTACT: Vanessa M. Meeks, Senior Counsel, or Parisa Haghshenas, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds (''ETFs'').[1] Fund shares will be purchased and redeemed at their NAV in Creation Units only. All orders to purchase Creation Units and all redemption requests will be placed by or through an ''Authorized Participant'', which will have signed a participant agreement with a broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act'') (together with any future distributor, the ''Distributor''). Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond generally to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act (''Affiliated Person''), or an affiliated person of an Affiliated Person (''Second-Tier Affiliate''), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the Distributor will compile, create, sponsor or maintain the Underlying Index.[2]

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments (''Deposit Instruments''), and shareholders redeeming their shares will receive specified instruments (''Redemption Instruments''). The Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units only.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c–1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fourteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to

[1] Applicants request that the order apply to the initial series of the Trust and any additional series of the Trust, and any other open-end management investment company or series thereof, that may be created in the future (each, included in the term ''Fund''), each of which will operate as an ETF and will track a specified index comprised of domestic or foreign equity and/or fixed income securities (each, an ''Underlying Index''). Any Fund will (a) be advised by CWM or an entity controlling, controlled by, or under common control with CWM (each, an ''Adviser'') and (b) comply with the terms and conditions of the application.

[2] Each Self-Indexing Fund will post on its Web site the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions and Deposit Instruments and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[3] The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Brent J. Fields,

Secretary.

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[3] The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79445; File No. SR–NYSEArca–2016–152]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposal to Change Representation Regarding Investments by PowerShares DB Trust Issued Receipts Listed Under Commentary .02 to NYSE Arca Equities Rule 8.200

December 1, 2016.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 18, 2016, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to change a representation regarding investments by the following issues, which are currently listed on the Exchange under Commentary .02 to NYSE Arca Equities Rule 8.200 (Trust Issued Receipts): PowerShares DB Commodity Index Tracking Fund; PowerShares DB Energy Fund; PowerShares DB Oil Fund; PowerShares DB Precious Metals Fund; PowerShares DB Gold Fund; PowerShares DB Silver Fund; PowerShares DB Base Metals Fund; PowerShares DB Agriculture Fund; PowerShares DB G10 Currency Harvest Fund; PowerShares DB US Dollar Index Bullish Fund; and PowerShares DB US Dollar Index Bearish Fund. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange currently lists and trades shares of the following securities under Commentary .02 to NYSE Arca Equities Rule 8.200 (Trust Issued Receipts): PowerShares DB Commodity Index Tracking Fund; PowerShares DB Energy Fund; PowerShares DB Oil Fund; PowerShares DB Precious Metals Fund; PowerShares DB Gold Fund; PowerShares DB Silver Fund; PowerShares DB Base Metals Fund; PowerShares DB Agriculture Fund; PowerShares DB G10 Currency Harvest Fund; PowerShares DB US Dollar Index Bullish Fund; and PowerShares DB US Dollar Index Bearish Fund (each a ''Fund'' and, collectively, the ''Funds'').[4]

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Shares of each Fund represent beneficial ownership interests in the Fund's net assets, as described in the registration statements for the Funds. *See* the following registration statements on Form S–3 or Form S–1 under the Securities Act of 1933: (1) Registration statement on Form S–3ASR, PowerShares DB Commodity Index Tracking Fund (No. 333–203054, dated March 27, 2015); (2) registration statement on Form S–3, PowerShares DB G10 Currency Harvest Fund (No. 333–192126, December 6, 2013); (3) registration statement on Form S–3ASR, PowerShares DB US Dollar Index Bullish Fund (No. 333–207089–01, September 23, 2015); (4) registration statement on Form S–1, PowerShares DB US Dollar Index Bearish Fund (No. 333–193224, March 14, 2014); (5) registration

Shares of the Funds were originally approved for listing on the American Stock Exchange LLC (''Amex'') (now known as NYSE MKT LLC),[5] and were subsequently approved for listing on the Exchange.[6] The Funds' Managing Owner is Invesco PowerShares Capital Management LLC.

Each Fund seeks to track an index of commodity or currency futures. As described in the Amex Filings and UTP Filings, the cash proceeds of the issuance of each Fund's Shares are invested in cash and United States Treasury Securities (''Treasury Securities''), some of which are deposited with a futures commission merchant as margin for futures positions. The Exchange proposes to add to this representation that a Fund may gain exposure to Treasury Securities, for cash management and/or margin purposes, through an investment in (1) government money market funds (as defined in Rule 2a–7 under the Investment Company Act of 1940 (''1940 Act'')[7]), and (2) exchange-traded funds that track indexes that measure the performance of U.S. Treasury obligations with a maximum remaining maturity of up to 12 months (''T-Bill ETFs'').[8] The Funds may receive dividends or distributions of capital gains from such investment in government money market funds and T-Bill ETFs.

The Funds' Managing Owner (Invesco PowerShares Capital Management LLC) represents that the proposed change to permit investment in T-Bill ETFs, as described above, is consistent with each Fund's investment objective, and will further assist the Funds' Managing Owner to achieve each Fund's investment objective. Specifically, by investing in government money market funds and T-Bill ETFs, in addition to U.S. Treasury Securities, each Fund will have additional flexibility to gain exposure to Treasury Securities. Except for the changes noted above, all other representations made in the Amex Filings and UTP Filings remain unchanged. The Funds will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.200.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[9] that an exchange have rules that are 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, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that trading in government money market funds and T-Bill ETFs occurs in transparent, liquid markets in the U.S. By investing in government money market funds and T-Bill ETFs, in addition to U.S. Treasury Securities, each Fund will have additional flexibility to gain exposure to Treasury Securities. The Adviser represents that the respective investment objectives of the Funds have not changed.

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 purpose of the Act. The Exchange believes the proposed rule change, which would permit each Fund to utilize government money market funds and T-Bill ETFs for cash management and/or margin purposes, will enhance competition among issues of Trust Issued Receipts that invest in commodity and currency futures.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because each Fund is already permitted to seek exposure to Treasury Securities, and the proposed rule change will merely provide each Fund with additional flexibility to gain such exposure through investments in government money market funds and T-Bill ETFs, which trade in transparent, liquid markets in the United States. Therefore, the Commission designates

statement on Form S–3, PowerShares DB Energy Fund, PowerShares DB Oil Fund, PowerShares DB Precious Metals Fund, PowerShares DB Gold Fund, PowerShares DB Base Metals Fund, (No. 333–209437–01—333–209437–05, March 4, 2016); (6) registration statement on Form S–1, PowerShares DB Silver Fund (No. 333–193222, March 14, 2014); and (7) registration statement on Form S–3ASR, PowerShares DB Agriculture Fund (No. 333–208439–01, dated December 10, 2015) (collectively, ''Registration Statements'').

[5] *See* Securities Exchange Act Release Nos. 53105 (January 11, 2006), 71 FR 3129 (January 19, 2006) (SR–Amex–2005–59) (approving listing of DB Commodity Index Tracking Fund (now known as PowerShares DB Commodity Index Tracking Fund)); 55292 (February 14, 2007), 72 FR 8406 (February 26, 2007) (SR–Amex–2006–86) (approving listing of the PowerShares DB US Dollar Index Bullish Fund and PowerShares DB US Dollar Index Bearish Fund); 54450 (September 14, 2006), 71 FR 55230 (September 21, 2006) (SR–Amex–2006–44) (approving listing of DB Currency Index Value Fund (now known as PowerShares DB G10 Currency Harvest Fund)); 55029 (December 29, 2006), 72 FR 806 (January 8, 2007) (SR–Amex–2006–76) (approving listing of PowerShares DB Energy Fund, PowerShares DB Oil Fund, PowerShares DB Precious Metals Fund, PowerShares DB Gold Fund, PowerShares DB Silver Fund, the PowerShares DB Base Metals Fund, and PowerShares DB Agriculture Fund) (collectively, ''Amex Filings'').

[6] *See* Securities Exchange Act Release No. 58993 (November 21, 2008), 73 FR 72548 (November 28, 2008) (SR–NYSEArca–2008–128) (order approving listing on the Exchange of the Funds) (''NYSE Arca Order''). The Funds were previously traded on the Exchange pursuant to unlisted trading privileges (''UTP''). *See* Securities Exchange Act Release Nos. 53736 (April 27, 2006), 71 FR 26582 (May 5, 2006) (SR–PCX–2006–22) (order approving UTP trading of DB Commodity Index Tracking Fund); 55453 (March 13, 2007), 72 FR 13333 (March 21, 2007) (SR–NYSEArca–2006–62) (order approving UTP trading of PowerShares DB Agriculture Fund and other PowerShares commodity-based funds) (collectively, ''UTP Filings'').

[7] 15 U.S.C. 80a–1. Rule 2a–7(a)(14) under the 1940 Act states that government money market fund means a money market fund that invests 99.5 percent or more of its total assets in cash, government securities, and/or repurchase agreements that are collateralized fully.

[8] The T-Bill ETFs in which a Fund may invest may be affiliated with the Managing Owner and will be registered under the 1940 Act. For purposes of this filing, T-Bill ETFs include Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); and Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600). Such T-Bill ETFs all will be listed and traded in the U.S. on registered exchanges. The Funds will not invest in inverse, leveraged or inverse leveraged (*e.g.,* –1X, 2X, –2X, 3X or –3X) T-Bill ETFs.

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

the proposed rule change to be operative upon filing.[12]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–152 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–152. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–152 and should be submitted on or December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29290 Filed 12–6–16; 8:45 am]

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[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 15 U.S.C. 78s(b)(2)(B).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79443; File No. SR–NYSEMKT–2016–109]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Rules Governing Business Continuity and Disaster Recovery Planning

December 1, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 22, 2016, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') 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

The Exchange proposes to amend its rules governing business continuity and disaster recovery to delete Rule 49—Equities (Emergency Powers) and set an operative date for Rule 49—Equities (Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules governing business continuity and disaster recovery to delete Rule 49—Equities (Emergency Powers) (''Print as P Rule'') and set an operative date for Rule 49—Equities (Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing) (''Rule 49''). The Exchange proposes to make these changes because the Exchange has completed testing of the operation of Rule 49 in its Disaster Recovery ''DR'' facility and therefore plans to implement it. Accordingly, the Exchange proposes to delete its Print as P Rule as obsolete, with an operative date of November 23, 2016.

On September 29, 2016, the Commission approved amendments to the Exchange's business continuity and disaster recovery plans.[4] In that filing, the Exchange added the following preamble to the Print as P Rule:

This version of Rule 49—Equities will remain operative until the proposed rule changes described in SR–NYSEMKT–2016–68 are approved and the Exchange files a separate proposed rule change to delete this version of Rule 49—Equities and preamble and to establish the operative date of paragraph (a) of ''Rule 49—Equities. Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing.'' Subject to such separate proposed rule change, the Exchange will announce via Trader

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 78917 (September 23, 2016), 81 FR 67036 (September 29, 2016) (SR–NYSEMKT–2016–68) (order granting approval of proposed rule change, as modified by Amendment No. 1 and Partial Amendment No. 2).

Update the operative date of the deletion of this Rule and implementation of paragraph (a) of Rule 49—Equities. Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing.

In addition, the Exchange added the following preamble to Rule 49 and added an ''N'' modifier to Rule 49(b), to distinguish it from paragraph (b) of the Print as P Rule.

The Exchange will file a separate proposed rule change to establish the operative date of paragraph (a) of this version of Rule 49—Equities and to delete ''Rule 49—Equities. Emergency Powers'' and this preamble. Until such time, ''Rule 49—Equities. Emergency Powers'' will remain operative. Subject to such separate proposed rule change, the Exchange will announce via Trader Update the operative date of paragraph (a) of this Rule and deletion of ''Rule 49—Equities. Emergency Powers.''

Member organizations required to test Exchange Backup Systems under paragraph (b)(N) of this Rule will be required to test trading on the Exchange's Disaster Recovery Facility under paragraph (a) of this Rule on date(s) to be determined by the Exchange. Such mandatory testing dates will be announced by Trader Update.

On November 5 and 19, 2016, the Exchange held the mandatory testing sessions for the operation of Rule 49 in the DR facility.[5] The Exchange has determined that these tests were successful because all member organizations required to test trading on the Exchange's DR facility, as specified in the second paragraph of the preamble to Rule 49, participated in the tests and the DR facility operated as provided for in Rule 49. Accordingly, the Exchange proposes to retire its Print as P Rule and implement Rule 49 operative November 23, 2016.

The Exchange therefore proposes to:

- Delete the Print as P Rule, including the preamble;
- Delete the explanatory preamble to Rule 49; and
- Delete the ''N'' modifier to new Rule 49(b), which distinguished new Rule 49(b) from the Print as P Rule 49(b).

In addition to this proposed rule change, the Exchange proposes to announce the operative date of November 23, 2016 via Trader Update.[6]

2. Statutory Basis

The proposed rule changes are consistent with Section 6(b) of the Act,[7] in general, and further the objectives of Section 6(b)(5) of the Act,[8] in particular, in that they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

In particular, the Exchange believes that amending its rules to delete the Print as P Rule, which is no longer operative after the successful completion of mandatory testing by the Exchange's member organizations of the operation of Rule 49, would promote the protection of investors and the public interest because it would promote clarity and transparency on the Exchange rules governing the Exchange's business continuity and disaster recovery planning. The Exchange further believes that deleting the superseded rule that was applicable only to the prior disaster recovery plan, deleting the preamble to Rule 49, and deleting the ''N'' modifier that distinguished the new rule from the now obsolete rule would remove impediments to and perfect the mechanism of a national market system because these proposed changes would add greater clarity to the Exchange's rules and promote market transparency and efficiency.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address competitive issues but rather is designed to facilitate trading in Exchange-listed securities on its DR facility. As such, the Exchange believes that the proposed rule change would promote competition for the benefit of market participants and investors generally because it provides transparency on the Exchange rules which would govern trading in Exchange traded securities if they trade on the Exchange's DR facility and greater efficiency and transparency concerning trading on the Exchange in the event of a disaster.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[12] the Commission may 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 immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because doing so would allow the Exchange to more quickly implement a business continuity and disaster recovery plan under which the Exchange no longer relies on the facilities of an affiliated exchange. Therefore, the Commission hereby

[5] The Exchange announced by Trader Update that industry tests would be held on November 5, 2016 and November 19, 2016. *See* NYSE Trader Updates, dated September 9 and 16, 2016, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_and_NYSE_MKT_DR_Trader_Update_Final.pdf* and *https://www.nyse.com/publicdocs/nyse/markets/nyse/DR_Testing.pdf.*

[6] New York Stock Exchange LLC, the Exchange's affiliate, has also submitted substantially the same proposed rule change to propose the same changes as described herein. *See* SR–NYSE–2016–81. In addition, NYSE Arca, Inc., the Exchange's affiliate, has submitted a proposed rule change to delete NYSE Arca Equities Rule 2.100, which allowed it to act on behalf of and at the direction of the Exchange if the Exchange invoked its Print as P Rule. *See* SR–NYSEArca–2016–154.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2016–109 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–109. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–109 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29288 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[13] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79444; File No. SR–NYSE–2016–81]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Rules Governing Business Continuity and Disaster Recovery

December 1, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 22, 2016, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing business continuity and disaster recovery to delete Rule 49 (Emergency Powers) and set an operative date for Rule 49 (Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules governing business continuity and disaster recovery to delete Rule 49 (Emergency Powers) (''Print as P Rule'') and set an operative date for Rule 49 (Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing) (''Rule 49''). The Exchange proposes to make these changes because the Exchange has completed testing of the operation of Rule 49 in its Disaster Recovery ''DR'' facility and therefore plans to implement it. Accordingly, the Exchange proposes to delete its Print as P Rule as obsolete, with an operative date of November 23, 2016.

On September 29, 2016, the Commission approved amendments to the Exchange's business continuity and disaster recovery plans.[4] In that filing, the Exchange added the following preamble to the Print as P Rule:

This version of Rule 49 will remain operative until the proposed rule changes described in SR–NYSE–2016–48 are approved and the Exchange files a separate proposed rule change to delete this version of Rule 49 and preamble and to establish the operative date of paragraph (a) of ''Rule 49. Exchange Business Continuity and Disaster Recovery Plans and Mandatory

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 78916 (September 23, 2016), 81 FR 67029 (September 29, 2016) (SR–NYSE–2016–48) (order granting approval of proposed rule change, as modified by Amendment No. 1 and Partial Amendment No. 2).

Testing.'' Subject to such separate proposed rule change, the Exchange will announce via Trader Update the operative date of the deletion of this Rule and implementation of paragraph (a) of Rule 49. Exchange Business Continuity and Disaster Recovery Plans and Mandatory Testing.

In addition, the Exchange added the following preamble to Rule 49 and added an ''N'' modifier to Rule 49(b), to distinguish it from paragraph (b) of the Print as P Rule.

The Exchange will file a separate proposed rule change to establish the operative date of paragraph (a) of this version of Rule 49 and to delete ''Rule 49. Emergency Powers'' and this preamble. Until such time, ''Rule 49. Emergency Powers'' will remain operative. Subject to such separate proposed rule change, the Exchange will announce via Trader Update the operative date of paragraph (a) of this Rule and deletion of ''Rule 49. Emergency Powers.''

Member organizations required to test Exchange Backup Systems under paragraph (b)(N) of this Rule will be required to test trading on the Exchange's Disaster Recovery Facility under paragraph (a) of this Rule on date(s) to be determined by the Exchange. Such mandatory testing dates will be announced by Trader Update.

On November 5 and 19, 2016, the Exchange held the mandatory testing sessions for the operation of Rule 49 in the DR facility.[5] The Exchange has determined that these tests were successful because all member organizations required to test trading on the Exchange's DR facility, as specified in the second paragraph of the preamble to Rule 49, participated in the tests and the DR facility operated as provided for in Rule 49. Accordingly, the Exchange proposes to retire its Print as P Rule and implement Rule 49 operative November 23, 2016.

The Exchange therefore proposes to:

- Delete the Print as P Rule, including the preamble;
- Delete the explanatory preamble to Rule 49; and
- Delete the ''N'' modifier to new Rule 49(b), which distinguished new Rule 49(b) from the Print as P Rule 49(b).

In addition to this proposed rule change, the Exchange proposes to announce the operative date of November 23, 2016 via Trader Update.[6]

2. Statutory Basis

The proposed rule changes are consistent with Section 6(b) of the Act,[7] in general, and further the objectives of Section 6(b)(5) of the Act,[8] in particular, in that they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

In particular, the Exchange believes that amending its rules to delete the Print as P Rule, which is no longer operative after the successful completion of mandatory testing by the Exchange's member organizations of the operation of Rule 49, would promote the protection of investors and the public interest because it would promote clarity and transparency on the Exchange rules governing the Exchange's business continuity and disaster recovery planning. The Exchange further believes that deleting the superseded rule that was applicable only to the prior disaster recovery plan, deleting the preamble to Rule 49, and deleting the ''N'' modifier that distinguished the new rule from the now obsolete rule would remove impediments to and perfect the mechanism of a national market system because these proposed changes would add greater clarity to the Exchange's rules and promote market transparency and efficiency.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address competitive issues but rather is designed to facilitate trading in Exchange-listed securities on its DR facility. As such, the Exchange believes that the proposed rule change would promote competition for the benefit of market participants and investors generally because it provides transparency on the Exchange rules which would govern trading in Exchange traded securities if they trade on the Exchange's DR facility and greater efficiency and transparency concerning trading on the Exchange in the event of a disaster.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[12] the Commission may 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 immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because doing so would allow the Exchange to more quickly implement a business continuity and disaster recovery plan under which the Exchange no longer relies on the facilities of an affiliated exchange. Therefore, the Commission hereby

[5] The Exchange announced by Trader Update that industry tests would be held on November 5, 2016 and November 19, 2016. *See* NYSE Trader Updates, dated September 9 and 16, 2016, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_and_NYSE_MKT_DR_Trader_Update_Final.pdf* and *https://www.nyse.com/publicdocs/nyse/markets/nyse/DR_Testing.pdf.*

[6] NYSE MKT LLC, the Exchange's affiliate, has also submitted substantially the same proposed rule change to propose the same changes as described herein. *See* SR–NYSEMKT–2016–109. In addition, NYSE Arca, Inc., the Exchange's affiliate, has submitted a proposed rule change to delete NYSE Arca Equities Rule 2.100, which allowed it to act on behalf of and at the direction of the Exchange if the Exchange invoked its Print as P Rule. *See* SR–NYSEArca–2016–154.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtm*l); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2016–81 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–81. 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 Web site (*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 Web site 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–81 and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29289 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[13] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IA–4579; File No. 803–00237]

Robert W. Baird & Co. Incorporated; Notice of Application

December 1, 2016.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an exemptive order under section 206A of the Investment Advisers Act of 1940 (''Advisers Act'') providing an exemption from the written disclosure and consent requirements of section 206(3).

Applicant: Robert W. Baird & Co. Incorporated (''Applicant'').

Relevant Advisers Act Sections: Exemption requested under section 206A from the written disclosure and consent requirements of section 206(3).

Summary of Application: Applicant requests that the Commission issue an order under section 206A exempting it and Future Advisers (as defined below) from the written disclosure and consent requirements of section 206(3) with respect to principal transactions with nondiscretionary advisory client accounts.

Filing Dates: The application was filed on October 14, 2016 and amended on November 23, 2016.

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 December 27, 2016, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Advisers Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicant, Charles M. Weber, Managing Director, Robert W. Baird & Co. Incorporated, 777 East Wisconsin Avenue, Milwaukee, Wisconsin 53202 and Monica Lea Parry, Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Ave. NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Robert Shapiro, Senior Counsel, at (202) 551–7758 (Chief Counsel's Office, Division of Investment Management) or Melissa Harke, Senior Special Counsel, at (202) 551–6787 (Investment Adviser Regulation Office, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site at *http://www.sec.gov/rules/iareleases.shtml* or by calling (202) 551–8090.

Applicant seeks relief from the written disclosure and consent requirements of section 206(3) of the Advisers Act that would be similar to relief currently provided by Advisers Act rule 206(3)–3T (the ''Rule''), which will expire by its terms on December 31, 2016. The relief sought by Applicant, if granted, would be subject to conditions similar to those under the Rule, as well as certain revised or additional conditions.

Applicant's Representations

1. The Applicant is registered as an investment adviser with the Commission and is a registered broker-dealer. The Applicant is an employee-owned wealth management, capital markets, asset management, and private equity firm with operations in the United States, Europe, and Asia. The Applicant offers a number of advisory programs, including the Advisory

Choice Program (the ''Program''), a nondiscretionary advisory program.

2. The Applicant created the Program in 2007 to accommodate the conversion of many of the Applicant's fee-based brokerage accounts to nondiscretionary advisory accounts following the invalidation of former Rule 202(a)(11)–1 under the Advisers Act. When these accounts had been fee-based brokerage accounts, the Applicant, in its capacity as a broker-dealer, engaged in principal transactions with its customers in accordance with applicable law. The Applicant currently relies on the Rule to engage in principal transactions with its client accounts in the Program.

3. The Applicant currently has approximately 34,000 client accounts enrolled in the Program. Those accounts have approximately $14 billion in assets under management as of June 30, 2016. In the period January 1, 2015 through December 31, 2015, 890 trades were effected in reliance on the Rule in the Program. Approximately 81% percent of the trades done in reliance on the Rule in this period were purchases by client accounts; the average purchase was approximately $48,000. Approximately 19% percent of the trades done in reliance on the Rule in this period were sales from client accounts; the average sale was approximately $51,000.

4. For the 12-month periods ended December 31, 2014, and December 31, 2015, the Applicant did not rely on the Rule to engage in principal trades in investment-grade fixed income securities it underwrote.

5. The Applicant acknowledges that the Order, if granted, would not be construed as relieving in any way the Applicant from acting in the best interests of an advisory client, including fulfilling the duty to seek the best execution for the particular transaction for the advisory client; nor shall it relieve the Applicant from any obligation that may be imposed by sections 206(1) or (2) of the Advisers Act or by other applicable provisions of the federal securities laws or applicable FINRA rules.

Applicant's Legal Analysis

1. Section 206(3) provides that it is unlawful for any investment adviser, directly or indirectly, acting as principal for its own account, knowingly to sell any security to or purchase any security from a client, without disclosing to the client in writing before the completion of the transaction the capacity in which the adviser is acting and obtaining the client's consent to the transaction. Rule 206(3)–3T deems an investment adviser to be in compliance with the provisions of section 206(3) of the Advisers Act when the investment adviser, or a person controlling, controlled by, or under common control with the investment adviser, acting as principal for its own account, sells to or purchases from an advisory client any security, provided that the investment adviser complies with the conditions of the Rule.

2. Rule 206(3)–3T requires, among other things, that the investment adviser obtain a client's written, revocable consent prospectively authorizing the adviser, directly or indirectly, acting as principal for its own account, to sell any security to or purchase any security from the client. The consent must be obtained after the adviser provides the client with written disclosure about: (i) The circumstances under which the investment adviser may engage in principal transactions with the client; (ii) the nature and significance of the conflicts the investment adviser has with its client's interests as a result of those transactions; and (iii) how the investment adviser addresses those conflicts. The investment adviser also must provide trade-by-trade disclosure to the client, before the execution of each principal transaction, of the capacity in which the adviser may act with respect to the transaction, and obtain the client's consent (which may be written or oral) to the transaction. The Rule is available only to an investment adviser that is also a broker-dealer registered under section 15 of the Securities Exchange Act of 1934 (''Exchange Act'') and may only be relied upon with respect to a nondiscretionary account that is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member. Rule 206(3)–3T is not available for principal transactions if the investment adviser or a person who controls, is controlled by, or is under common control with the adviser (''control person'') is the issuer or is an underwriter of the security, except that an adviser may rely on the Rule for trades in which the adviser or a control person is an underwriter of non-convertible investment-grade debt securities.

3. The investment adviser also must provide to the client a trade confirmation that, in addition to the requirements of rule 10b–10 under the Exchange Act, includes a conspicuous, plain English statement informing the client that the investment adviser disclosed to the client before the execution of the transaction that the investment adviser may act as principal in connection with the transaction, that the client authorized the transaction, and that the investment adviser sold the security to or bought the security from the client for its own account. The investment adviser also must deliver to the client, at least annually, a written statement listing all transactions that were executed in the account in reliance on the Rule, including the date and price of each transaction.

4. Rule 206(3)–3T is scheduled to expire on December 31, 2016. Upon expiration, the Applicant would be required to provide trade-by-trade written disclosure to each nondiscretionary advisory client with whom the Applicant sought to engage in a principal transaction in accordance with section 206(3). The Applicant submits that its nondiscretionary clients, through the Applicant's current reliance on the Rule, have had access to the Applicant's inventory through principal transactions for a number of years, and expect to continue to have such access in the future. The Applicant believes that engaging in principal transactions with its clients provides certain benefits to its clients, including access to securities of limited availability, such as municipal bonds, and that the written disclosure and client consent requirements of section 206(3) act as an operational barrier to its ability to engage in principal trades with its clients, especially when the transaction involves securities of limited availability.

5. Unless the Applicant is provided an exemption from the written disclosure and client consent requirements of section 206(3), Applicant believes that it will be unable to provide the same range of services and access to the same types of securities to its nondiscretionary advisory clients as it currently is able to provide to clients under the Rule.

6. The Applicant notes that, if the requested relief is granted, it will remain subject to the fiduciary duties that are generally enforceable under sections 206(1) and 206(2) of the Advisers Act, which, in general terms, require the Applicant to: (i) Disclose material facts about the advisory relationship to its clients; (ii) treat each client fairly; and (iii) act only in the best interests of its client, disclosing conflicts of interest when present and obtaining client consent to arrangements that present such conflicts.

7. The Applicant further notes that, in its capacity as a broker-dealer with respect to these accounts, it will remain subject to a comprehensive set of Commission and FINRA regulations that apply to the relationship between a broker-dealer and its customer in

addition to the fiduciary duties an adviser owes a client. These rules require, among other things, that the Applicant deal fairly with its customers, seek to obtain best execution of customer orders, and make only suitable recommendations. These obligations are designed to promote business conduct that protects customers from abusive practices that may not necessarily be fraudulent, and to protect against unfair prices and excessive commissions. Specifically, these provisions, among other things, require that the prices charged by the Applicant be reasonably related to the prevailing market, and limit the commissions and mark-ups the Applicant can charge. Additionally, these obligations require that the Applicant have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer, based on information obtained through reasonable diligence.

8. The Applicant requests that the Commission issue an Order pursuant to section 206A exempting it from the written disclosure and consent requirements of section 206(3) only with respect to client accounts in the Program and any similar nondiscretionary program to be created in the future. The Applicant also requests that the Commission's Order apply to future investment advisers controlling, controlled by, or under common control with the Applicant (''Future Advisers''). Any Future Adviser relying on any Order granted pursuant to the application will comply with the terms and conditions stated in the application.[1]

Applicant's Conditions

The Applicant agrees that any Order granting the requested relief will be subject to the following conditions:

1. The Applicant will exercise no ''investment discretion'' (as such term is defined in section 3(a)(35) of the Exchange Act), except investment discretion granted by the advisory client on a temporary or limited basis,[2] with respect to the client's account.

2. The Applicant will not trade in reliance on this Order any security for which the Applicant or any person controlling, controlled by, or under common control with the Applicant is the issuer, or, at the time of the sale, an underwriter (as defined in section 202(a)(20) of the Advisers Act).

3. The Applicant will not directly or indirectly require the client to consent to principal trading as a condition to opening or maintaining an account with the Applicant.

4. The advisory client has executed a written revocable consent prospectively authorizing the Applicant directly or indirectly to act as principal for its own account in selling any security to or purchasing any security from the advisory client. The advisory client's written consent must be obtained through a signature or other positive manifestation of consent that is separate from or in addition to the signature indicating the client's consent to the advisory agreement. The separate or additional signature line or alternative means of expressing consent must be preceded immediately by prominent, plain English disclosure containing either: (a) An explanation of: (i) The circumstances under which the Applicant directly or indirectly may engage in principal transactions; (ii) the nature and significance of conflicts with its client's interests as a result of the transactions; and (iii) how the Applicant addresses those conflicts; or (b) a statement explaining that the client is consenting to principal transactions, followed by a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific page or pages on which such disclosure is located; provided, however, that if the Applicant requires time to modify its electronic systems to provide the specific page cross-reference required by clause (b), the Applicant may, while updating such electronic systems, and for no more than 90 days from the date of the Order, instead provide a cross-reference to a specific document provided to the client containing the disclosure in (a)(i)–(iii) above and to the specific section in such document in which such disclosure is located. *Transition provision:* To the extent that the Applicant obtained fully informed written revocable consent from an advisory client for purposes of rule 206(3)–3T(a)(3) prior to December 31, 2016, the Applicant may rely on this Order with respect to such client without obtaining additional prospective consent from such client.

5. The Applicant, prior to the execution of each transaction in reliance on this Order, will: (a) Inform the advisory client, orally or in writing, of the capacity in which it may act with respect to such transaction; and (b) obtain consent from the advisory client, orally or in writing, to act as principal for its own account with respect to such transaction.

6. The Applicant will send a written confirmation at or before completion of each such transaction that includes, in addition to the information required by rule 10b–10 under the Exchange Act, a conspicuous, plain English statement informing the advisory client that the Applicant: (a) Disclosed to the client prior to the execution of the transaction that the Applicant may be acting in a principal capacity in connection with the transaction and the client authorized the transaction; and (b) sold the security to, or bought the security from, the client for its own account.

7. The Applicant will send to the client, no less frequently than annually, written disclosure containing a list of all transactions that were executed in the client's account in reliance upon this Order, and the date and price of each such transaction.

8. The Applicant is a broker-dealer registered under section 15 of the Exchange Act and each account for which the Applicant relies on this Order is a brokerage account subject to the Exchange Act, and the rules thereunder, and the rules of the self-regulatory organization(s) of which it is a member.

9. Each written disclosure required as a condition to this Order will include a conspicuous, plain English statement that the client may revoke the written consent referred to in Condition 4 above without penalty at any time by written notice to the Applicant in accordance with reasonable procedures established by the Applicant, but in all cases such revocation must be given effect within 5 business days of the Applicant's receipt thereof.

10. The Applicant will maintain records sufficient to enable verification of compliance with the conditions of this Order. Such records will include, *without limitation:* (a) Documentation sufficient to demonstrate compliance with each disclosure and consent requirement under this Order; (b) in particular, documentation sufficient to demonstrate that, prior to the execution of each transaction in reliance on this

[1] All entities that currently intend to rely on any order granted pursuant to the application are named as Applicants.

[2] Discretion is considered to be temporary or limited for purposes of this condition when the investment adviser is given discretion: (i) As to the price at which or the time to execute an order given by a client for the purchase or sale of a definite amount or quantity of a specified security; (ii) on an isolated or infrequent basis, to purchase or sell a security or type of security when a client is unavailable for a limited period of time not to exceed a few months; (iii) as to cash management, such as to exchange a position in a money market fund for another money market fund or cash equivalent; (iv) to purchase or sell securities to satisfy margin requirements; (v) to sell specific bonds and purchase similar bonds in order to permit a client to take a tax loss on the original position; (vi) to purchase a bond with a specified credit rating and maturity; and (vii) to purchase or sell a security or type of security limited by specific parameters established by the client. *See, e.g., Temporary Rule Regarding Principal Trades with Certain Advisory Clients,* Investment Advisers Act Release No. 2653 (Sept. 24, 2007) at n. 31.

Order, the Applicant informed the advisory client of the capacity in which it may act with respect to the transaction and that it received the advisory client's consent (if the Applicant informs the client orally of the capacity in which it may act with respect to such transaction or obtains oral consent, such records may, for example, include recordings of telephone conversations or contemporaneous written notations); and (c) documentation sufficient to enable assessment of compliance by the Applicant with sections 206(1) and (2) of the Advisers Act in connection with its reliance on this Order.[3] In each case, such records will be maintained and preserved in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

11. The Applicant will adopt written compliance policies and procedures reasonably designed to ensure, and the Applicant's chief compliance officer will monitor, the Applicant's compliance with the conditions of this Order. The Applicant's chief compliance officer will, on at least a quarterly basis, conduct testing reasonably sufficient to verify such compliance. Such written policies and procedures, monitoring and testing will address, *without limitation:* (a) Compliance by the Applicant with its disclosure and consent requirements under this Order; (b) the integrity and operation of electronic systems employed by the Applicant in connection with its reliance on this Order; (c) compliance by the Applicant with its recordkeeping obligations under this Order; and (d) whether there is any evidence of the Applicant engaging in ''dumping'' in connection with its reliance on this Order.[4] The Applicant's chief compliance officer will document the frequency and results of such monitoring and testing, and the Applicant will maintain and preserve such documentation in an easily accessible place for a period of not less than five years, the first two years in an appropriate office of the Applicant, and be available for inspection by the staff of the Commission.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2016–29298 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[3] For example, under sections 206(1) and (2), an adviser may not engage in any transaction on a principal basis with a client that is not consistent with the best interests of the client or that subrogates the client's interests to the adviser's own. *Cf.* Investment Advisers Act Release No. 2106 (Jan. 31, 2003) (adopting Rule 206(4)–6).

[4] *See* Report of the Securities and Exchange Commission, Investment Trusts and Investment Companies, H.R. Doc. No. 279, 76th Cong., 2d Sess., pt. 3, at 2581, 2589 (1939); Hearings on S.3580 Before a Subcommittee of the Commission on Banking and Currency, 76th Cong., 3d Sess. 209, 212–23 (1940); Hearings on S. 3580 Before the Subcomm. of the Comm. on Banking and Currency, 76th Cong., 3d Sess. 322 (1940).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79447; File No. SR–NASDAQ–2016–163]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Change the Titles of Equities Rule 7015 and Options Chapter XV, Section 3, and To Make Related Changes

December 1, 2016.

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 November 28, 2016, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') 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 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 the Substance of the Proposed Rule Change

The Exchange proposes to rename the title of rules that assess fees for connectivity to systems operated by the Exchange or FINRA under Equities Rule 7015 and Options Chapter XV, Section 3, and to make related changes to other rules that reference the renamed rules.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to rename related text in Rule 7015 and Chapter XV, Section 3, to more accurately reflect the services being provided and eliminate an outdated term. Both Rule 7015 and Chapter XV, Section 3, include connectivity to services that are not related to connecting to the Exchange trading system, such as TradeInfo,[3] Specialized Services Related to FINRA/NASDAQ Trade Reporting Facility,[4] and the NASDAQ IPO Workstation.[5] As a consequence, the Exchange believes that it is appropriate to rename the title of Rule 7015 as ''Ports and other Services'' and rename the title of Chapter XV, Section 3, as ''NASDAQ Options Market—Ports and other Services,'' which the Exchange believes more accurately describe the depth and breadth of services provided to members under those rules.

The Exchange is also proposing to amend reference to the title of Rule 7015 in Rule 7007(a), which is titled ''Collection of Exchange Fees and Other Claims and Billing Policy,'' and is also amending reference to the title of Chapter XV, Section 3, found under Section 7(c)(2) of Chapter XV to reflect the amended titles of Rule 7015 and Chapter XV, Section 3.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] TradeInfo is an Internet-based tool that, among other things, allows users to view all of the NASDAQ order and execution information for their entire firm for both equities and options through a single interface. TradeInfo may be subscribed to under both Rule 7015 and Chapter XV Section 3.

[4] Specialized Services Related to FINRA/NASDAQ Trade Reporting Facility includes WebLink ACT or Nasdaq Workstation Post Trade, and ACT Workstation. *See* Rule 7015(e).

[5] The NASDAQ IPO Workstation provides subscribing member firms with the IPO Indicator service, which provides information on order execution that would be received in an IPO during the launch process.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

in particular, in that it is designed 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, by clarifying applicability of rules whose current titles could confuse market participants. Specifically, the Exchange is eliminating the term ''Access'' and replacing it with the phrase ''Ports and other'' because the new titles will more accurately describe the depth and breadth of services provided to members under Rule 7015 and Chapter XV, Section 3. As explained above, the various connectivity and services offered under Rule 7015 and Chapter XV, Section 3, include services listed that are not related to connecting to the Exchange such as TradeInfo, Specialized Services Related to FINRA/NASDAQ Trade Reporting Facility, or the NASDAQ IPO Workstation. These services allow members to view information and are not related to connecting to the Exchange. Thus, the changes proposed herein do not impact the fees, connectivity or services described under Rule 7015 and Chapter XV, Section 3, but rather merely clarify and harmonize the terminology used to better align it with what is provided under the rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that, to the extent it has any impact on competition, the proposed change will promote competition by making it clear to all market participants and exchange competitors what is provided under Rule 7015 and Chapter XV, Section 3.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [8] and subparagraph (f)(6) of Rule 19b–4 thereunder.[9]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [10] 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 requested that the Commission waive the 30-day operative delay so that the proposed rule change will become operative on filing. The Exchange stated that the proposed rule change promotes the protection of investors and the public interest by clarifying and harmonizing the terminology used in the Exchange's rules. Waiver of the operative delay would allow the Exchange, without delay, to rename the rules to make clear what the rules cover, therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing.[11]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2016–163 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–163. 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 Web site (*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 Web site 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 the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–163, and should be submitted on or before December 28, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2016–29292 Filed 12–6–16; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(b)(3)(A)(iii).

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[12] 17 CFR 200.30–3(a)(12).

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36079]

CCET, LLC—Lease and Operation Exemption—Rail Line of Norfolk Southern Railway Company in Adams County, Ohio.

CCET, LLC (CCET), a Class III carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Norfolk Southern Railway Company (NSR) and operate a portion of NSR's CT Line, between milepost CT 62.20, east of Seaman, Ohio, and milepost CT 78.45, at Mineral Springs, Ohio (Line Extension).

CCET and NSR previously entered into a lease agreement on March 14, 2014, under which CCET leased a 24-mile portion of the CT Line between milepost CT 9.0 at Clare, Ohio, and milepost CT 32.83, west of Williamsburg, Ohio.[1] CCET and NSR also entered into an amendment to the lease agreement on December 9, 2014, to extend the lease approximately 29 miles from milepost CT 32.83, west of Williamsburg, Ohio, to milepost CT 62.20, east of Seaman, Ohio.[2] The parties now desire to further amend the lease to include the Line Extension to the east to allow CCET to pursue additional commercial opportunities.[3]

CCET states that the lease between CCET and NSR does not contain any provision that prohibits, restricts, or would otherwise limit future interchange of traffic with any third-party carrier.

CCET has certified that its projected annual revenues as a result of this transaction will not result in CCET's becoming a Class II or Class I rail carrier and will not exceed $5 million.

CCET states that the lease and operation of the Line Extension will commence on or after December 21, 2016, the effective date of the exemption (30 days after the verified notice of exemption was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than December 14, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36079 must be filed with Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on James H. M. Savage, 22 Rockingham Court, Germantown, MD 20874.

According to CCET, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at ''*WWW.STB.GOV.*''

Decided: December 2, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2016–29347 Filed 12–6–16; 8:45 am]

BILLING CODE 4915–01–P

[1] *See CCET, LLC—Lease & Operation Exemption—Rail Line of Norfolk S. Ry.,* FD 35810 (STB served Apr. 4, 2014).

[2] *See CCET, LLC—Lease & Operation Exemption—Rail Line of Norfolk S. Ry. in Clermont, Brown, & Adams Ctys.,Ohio,* FD 35900 (STB served Feb. 6, 2015).

[3] NSR previously discontinued operations over the Line Extension. *See Norfolk S. Ry.—Discontinuance of Serv. Exemption—in Adams & Scioto Ctys., Ohio,* AB 290 (Sub-No. 373X) (STB served Dec. 3, 2014); *Norfolk S. Ry.—Discontinuance of Serv. Exemption—in Clermont, Brown, & Adams Ctys., Ohio,* AB 290 (Sub-No. 370X) (STB served Jan. 15, 2015). Upon reaching an agreement with CCET to amend CCET's existing lease to operate the Line Extension, NSR informed the Board that it is reactivating service and its common carrier obligation for the Line Extension. *See* NSR Notification Letter, Nov. 4, 2016, *Norfolk S. Ry.—Discontinuance of Serv. Exemption—in Clermont, Brown, & Adams Ctys., Ohio,* AB 290 (Sub-No. 370X).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice to Manufacturers of Airports In-Pavement Stationary Runway Weather Information Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for information.

SUMMARY: The FAA is considering issuing waivers to foreign manufactures of Active and/or Passive In-Pavement Stationary Runway Weather Information Systems that meet the requirements of FAA Advisory Circular (AC) 15015220–30, Airport Winter Safety and Operations. This notice requests information from manufactures of systems meeting the technical requirements to determine whether a waiver to the Buy American Preferences should be issued. Projects funded under the Airport Improvement Program (AIP) must meet the requirements of Buy American Preferences.

DATES: The information must be received by January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Mr. Carlos N. Fields, Airports Financial Assistance, APP 520, Rooms 619, FAA, 800 Independence Avenue SW., Washington, DC 20591, Telephone (202) 267–8826.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration (FAA) manages a Federal grant program for airports called the Airports Improvement Program (AIP). AIP grant recipients must follow 49 U.S.C. 50101, Buy American Preferences.

Under 49 U.S.C 50101(b)(3), the Secretary of Transportation may waive the Buy American Preference requirement if the goods are not produced in a sufficient and reasonably available amount or are not of a satisfactory quality.

The purpose of this notice is to request manufactures of both passive and active in-pavement runway surface condition sensor systems, both domestic and foreign, to advise FAA of the system that they manufacture and whether it can meet the FAA Advisory Circular technical requirements. To respond to this notice, manufactures are to submit a written statement confirming that they currently manufacture passive and/or active in-pavement runway weather information systems on their business letterhead and signed by an authorized designee. The FAA wants to determine if there is sufficient quantity of domestic manufactures capable of meeting the FAA technical requirements. If the FAA cannot find that there are enough U.S. manufactures, it may issue a nationwide waiver to the foreign manufacturers identified as being capable of meeting the technical requirements.

Technical Requirements: FAA Advisory Circular (AC) 150/5220–30, Airport Winter Safety and Operations recommend that in-pavements runway sensor systems comply with the performances and installations requirements of SAE Aerospace Recommended Practice 5533, Stationary Runway Weather Information System (In-pavement). The SAE specification is available for purchases at *http://www.sae.org.* Because the guidance and specification s in an Advisory Circular are mandatory for airport project using AIP grant funds, as in-pavement runway surface condition sensor system project that included any AIP grant funding must meet the requirements of SAE ARP5533.

After review, the FAA may issue a nationwide waiver to Buy American Preferences for foreign manufactures or United States manufactures that meet the Buy American preference requirements. Waivers would not be

issued for manufacturers that do not fully meet the technical requirements. This ''nationwide waiver'' would allow equipment to be used on airport projects without having to receive separate project waivers. Having a nationwide waiver allows projects to start quickly without have to wait for the Buyer American analysis to be completed for every project.

Items that have been granted a ''nationwide waiver'' can be found on the FAA Web site at: *http://www.faa.gov/airports/aip/buy_american/.*

Issued in Washington, DC, December 1, 2016.

Frank J. San Martin,

Manager, Airports Financial Assistance Division.

[FR Doc. 2016–29319 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No: FAA–2005–22842]

Notice of Opportunity To Participate: Criteria and Application Procedures for Participation in the Military Airport Program (MAP)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of criteria and application procedures.

SUMMARY: This document announces the criteria, application procedures, and schedule to be applied by the Secretary of Transportation in designating or redesignating a maximum of 15 current joint-use or former military airports (at any one time), seeking a designation or redesignation to participate in the MAP for the purposes of capital development funding assistance.

DATES: Applications must be received on or before February 6, 2017.

ADDRESSES: Submit a signed original of Standard Form (SF) 424, ''Application for Federal Assistance,'' prescribed by the Office of Management and Budget Circular A–102, available at *http://www.faa.gov/airports/aip/* along with all supporting and justifying documentation required by this notice. Applicant must specifically request to be considered for designation or redesignation to participate in the Fiscal Year (FY) 2017 MAP. Submission(s) should be sent to the Regional FAA Airports Division or Airports District Office that serves the airport. Applicants may find the proper office on the FAA Web site *http://www.faa.gov/airports/news_information/contact_info/regional/* or may contact the office below.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan DiMartino (*Jonathan.DiMartino@faa.gov*), Airports Financial Assistance Division (APP–500), Office of Airport Planning and Programming, Federal Aviation Administration (FAA), 800 Independence Avenue SW., Washington, DC 20591, (202) 267–8744.

SUPPLEMENTARY INFORMATION:

General Description of the Program

The MAP provides capital development assistance to civil airport sponsors of designated current joint-use military airfields or former military airports that are included in the FAA's National Plan of Integrated Airport Systems (NPIAS). Airports designated to the MAP may be able to receive grant funds from a set-aside (currently four percent of Airport Improvement Program (AIP) discretionary funds) for airport development, including certain projects not otherwise eligible for AIP assistance. These airports are also eligible to receive grants from other categories of AIP funding.

The Secretary considers for designation only current joint-use or former military airports that meet the criteria set forth under ''Designation Considerations,'' below.

Number of Airports

A maximum of 15 airports per fiscal year may participate in the MAP, of which three may be General Aviation (GA) airports. There are twelve slots available in FY 2017. Of the twelve slots available, there are two GA slots available in FY 2017.

Term of Designation

The maximum term is five fiscal years following designation. The FAA can designate airports for a period of less than five years. The FAA will evaluate the conversion needs of the airport in its capital development plan to determine the appropriate length of designation.

Redesignation

Previously designated airports may apply for redesignation to an additional term or terms that may not exceed five years per each. Those airports must meet current eligibility requirements outlined in 49 U.S.C. 47118(a) at the beginning of each grant period. The FAA will evaluate applications for redesignation primarily in terms of justified projects specifically fundable only under the MAP as redesignees generally tend to have fewer conversion needs than new candidates. The FAA's goal is to graduate MAP airports to regular AIP participation by successfully converting these airports to civilian airport operations.

Eligible Projects

In addition to eligible AIP projects, the MAP can fund fuel farms, utility systems, surface automobile parking lots, hangars, and air cargo terminals up to 50,000 square feet. A designated or redesignated military airport can receive not more than $7,000,000 in each fiscal year to construct, improve, or repair terminal building facilities. In addition, a designated or redesignated military airport can receive not more than $7,000,000 each fiscal year for MAP eligible projects including hangars, cargo facilities, fuel farms, automobile surface parking, or utility work.

Designation Considerations

The MAP allows the Secretary of Transportation to designate current joint-use or former military airports (other than an airport so designated before August 24, 1994) to receive grants from the AIP if they meet the following general requirements:

(1) The airport is a former military installation closed or realigned under:

(a) Section 2687 of title 10 (announcement of closures of large Department of Defense installations after September 30, 1977);

(b) Section 201 of the Defense Authorization Amendments and Base Closure and Realignment Act (BRAC) (10 U.S.C. 2687 note); or

(c) Section 2905 of the Defense Base Closure and Realignment Act of 1990 (10 U.S.C. 2687 note); or

(2) The airport is a military installation with both military and civil aircraft operations; and

(3) The airport is classified as a commercial service or reliever airport in the NPIAS. (See 49 U.S.C. 47105(b)(2)). In addition, three of the designated airports, if included in the NPIAS, may be GA airports that were former military installations closed or realigned under BRAC, as amended, or 10 U.S.C. 2687. (See 49 U.S.C. 47118(g)). Therefore, a GA airport can only qualify under (1) above. ''General aviation airport'' means a public airport that is located in a State that, as determined by the Secretary: (A) does not have scheduled service; or (B) has scheduled service with fewer than 2,500 passenger boardings per year.

In designating new candidate airports, the Secretary shall consider if a grant will:

(1) Reduce delays at an airport with more than 20,000 hours of annual

delays in commercial passenger aircraft takeoffs and landings; or

(2) Enhance airport and air traffic control system capacity in a metropolitan area or reduce current and projected flight delays.

The application for new designations will be evaluated in terms of how the proposed projects will contribute to reducing delays and/or how the airport will enhance air traffic or airport system capacity and provide adequate user services.

Project Evaluation

Recently realigned or closed military airports, as well as active military airfields with new joint-use agreements, generally have the greatest need of funding assistance for conversion to or incorporation of civil airport operations. Newly converted airports and new joint-use locations frequently have minimal capital development resources and will therefore receive priority consideration for designation and MAP funding. The FAA will evaluate the need for eligible projects based upon information in the candidate airport's five-year Capital Improvement Plan (CIP).

(1) The FAA will evaluate candidate airports and any reliever role that they may perform for nearby airports based on the following specific factors:

- Compatibility of airport roles and the ability of the airport to provide an adequate airport facility;
- The capability of the candidate airport and its airside and landside complex to serve aircraft that otherwise must use a congested airport;
- Landside surface access;
- Airport operational capability, including peak hour and annual capacities of the candidate airport;
- Potential of other metropolitan area airports to relieve the congested airport;
- Ability to satisfy, relieve, or meet air cargo demand within the metropolitan area;
- Forecasted aircraft and passenger levels, type of commercial service anticipated, *i.e.* scheduled or chartered commercial service;
- Type and capacity of aircraft projected to serve the airport and level of operations at the congested airport and the candidate airport;
- The potential for the candidate airport to be served by aircraft or users, including the airlines, serving the congested airport;
- Ability to replace an existing commercial service or reliever airport serving the area; and
- Any other documentation to support the FAA designation of the candidate airport.

(2) The FAA will evaluate the extent to which development needs funded through the MAP will make the airport a viable civilian airport that will enhance system capacity or reduce delays.

Application Procedures and Required Documentation

Airport sponsors applying for designation or redesignation must complete and submit an SF–424, Application for Federal Assistance, and provide supporting documentation to the appropriate FAA Airports regional or district office serving that airport. Sponsors may obtain this fillable form at *http://www.faa.gov/airports/aip/.*

Applicants must fill out this form completely, including the following:

- Mark Item 1, Type of Submission as a ''pre-application'' and indicate it is for ''construction''.
- Mark item 8, Type of Application as ''new'', and in ''other'', fill in ''Military Airport Program''.
- Fill in Item 11, Descriptive Title of Applicant's Project. ''Designation (or redesignation) to the Military Airport Program''.
- Under Item 15a, Estimated Funding, indicate the total amount of funding requested from the MAP during the entire term for which you are applying.

Supporting Documentation

A. Identification as a Current or Former Military Airport. The application must identify the airport as either a current or former military airport and indicate whether it was:

(1) Closed or realigned under Section 201 of the Defense Authorization Amendments and Base Closure and Realignment Act, and/or Section 2905 of the Defense Base Closure and Realignment Act of 1990 (Installations Approved for Closure by the Defense Base Realignment and Closure Commissions), or

(2) Closed or realigned pursuant to 10 U.S.C. § 2687 as excess property (bases announced for closure by Department of Defense (DOD) pursuant to this title after September 30, 1977 (this is the date of announcement for closure)), or

(3) A military installation with both military and civil aircraft operations. A general aviation airport applying for the MAP may be joint-use but must also qualify under (1) or (2) above.

B. Qualifications for MAP. Submit documents for (1) through (8) below:

(1) Documentation that the airport meets the definition of a ''public airport'' as defined in 49 U.S.C. § 47102(20).

(2) Documentation indicating the required environmental review for civil reuse or joint-use of the military airfield has been completed. This environmental review need not include review of the individual projects to be funded by the MAP. Rather, the documentation must reflect that the environmental review necessary to convey the property, enter into a long-term lease, or finalize a joint-use agreement has been completed. The military department conveying or leasing the property, or entering into a joint-use agreement, has the lead responsibility for this environmental review. To meet AIP requirements, the environmental reviews and approvals must indicate that the operator or owner of the airport has good title that is satisfactory to the Secretary or assures, to the FAA's satisfaction, that good title will be acquired.

(3) For a former military airport, documentation that the eligible airport sponsor holds or will hold satisfactory title, a long-term lease in furtherance of conveyance of property for airport purposes, or a long-term interim lease for 25 years or longer to the property on which the civil airport is being located. Documentation that an application for surplus or BRAC airport property has been accepted by the Federal Government is sufficient to indicate the eligible airport sponsor holds or will hold satisfactory title or a long-term lease.

(4) For a current military airport, documentation that the airport sponsor has an existing joint-use agreement with the military department having jurisdiction over the airport. For all first time applicants, a copy of the existing joint-use agreement must be submitted with the application. This is necessary so the FAA can legally issue grants to the sponsor. Here and in (3) directly above, the airport must possess the necessary property rights in order to accept a grant for its proposed projects during FY 2016.

(5) Documentation that the airport is classified as a ''commercial service airport'' or a ''reliever airport'' as defined in 49 U.S.C. 47102(7) and 47102(23).

(6) Documentation that the airport owner is an eligible airport ''sponsor,'' as defined in 49 U.S.C. 47102(26).

(7) Documentation that the airport has a five-year CIP indicating all eligible grant projects requested to be funded either from the MAP or other portions of the AIP and an FAA approved Airport Layout Plan (ALP).

(8) For commercial service airports, a business/marketing plan or equivalent must be submitted with the application. For relievers or general aviation

airports, other planning documents may be submitted.

C. Evaluation Factors. Submit information on the items below to assist in the FAA's evaluation:

(1) Information identifying the existing and potential levels of visual or instrument operations and aeronautical activity at the current or former military airport and, if applicable, the congested airport. Also, if applicable, information on how the airport contributes to the air traffic system or airport system capacity. If served by commercial air carriers, the revenue passenger and cargo levels must be provided.

(2) A description of the airport's projected civil role and development needs for transitioning from use as a military airfield to a civil airport. Include how development projects would serve to reduce delays at an airport with more than 20,000 hours of annual delays in commercial passenger aircraft takeoffs and landings; or enhance capacity in a metropolitan area or reduce current and projected flight delays.

(3) A description of the existing airspace capacity. Describe how anticipated new operations would affect the surrounding airspace and air traffic flow patterns in the metropolitan area in or near the airport. Include a discussion of whether operations at this airport create airspace conflicts that may cause congestion or whether air traffic works into the flow of other air traffic in the area.

(4) A description of the airport's five-year CIP, including a discussion of major projects, their priorities, projected schedule for project accomplishment, and estimated costs. The CIP must specifically identify the safety, capacity, and conversion related projects, associated costs, and projected five-year schedule of project construction, including those requested for consideration for MAP funding.

(5) A description of those projects that are consistent with the role of the airport and effectively contribute to the joint-use or conversion of the airfield to a civil airport. The projects can be related to various improvement categories depending on what is needed to convert from military to civil airport use, to meet required civil airport standards, and/or to provide capacity to the airport and/or airport system. The projects selected (*e.g.,* safety-related, conversion-related, and/or capacity-related) must be identified and fully explained based on the airport's planned use. Those projects that may be eligible under MAP, if needed for conversion or capacity-related purposes, must be clearly indicated and include the following information:

Airside

- Modification of airport or military airfield for safety purposes, including airport pavement modifications, marking, lighting, strengthening, drainage or modifying other structures or features in the airport environs to meet civil standards for approach, departure and other protected airport surfaces as described in 14 CFR part 77 or standards set forth in FAA Advisory Circular 150/5300–13.
- Construction of facilities or support facilities, such as passenger terminal gates, aprons for passenger terminals, taxiways to new terminal facilities, aircraft parking, and cargo facilities to accommodate civil use.
- Modification of airport or military utilities (electrical distribution systems, communications lines, water, sewer, storm drainage) to meet civil standards. Also, modifications that allow utilities on the civil airport to operate independently, where other portions of the base are conveyed to entities other than the airport sponsor or retained by the Government.
- Purchase, rehabilitation, or modification of airport and airport support facilities and equipment, including snow removal, aircraft rescue, firefighting buildings and equipment, airport security, lighting vaults, and reconfiguration or relocation of eligible buildings for more efficient civil airport operations.
- Modification of airport or military airfield fuel systems and fuel farms to accommodate civil aviation use.
- Acquisition of additional land for runway protection zones, other approach protection, or airport development.
- Cargo facility requirements.
- Modifications which will permit the airfield to accommodate general aviation users.

Landside

- Construction of surface parking areas and access roads to accommodate automobiles in the airport terminal and air cargo areas and provide an adequate level of access to the airport.
- Construction or relocation of access roads to provide efficient and convenient movement of vehicular traffic to, on, and from the airport, including access to passenger, air cargo, fixed base operations, and aircraft maintenance areas.
- Modification or construction of facilities such as passenger terminals, surface automobile parking lots, hangars, air cargo terminal buildings, and access roads to cargo facilities to accommodate civil use.

(6) An evaluation of the ability of surface transportation facilities (*e.g.,* road, rail, high-speed rail, and/or maritime) to provide intermodal connections.

(7) A description of the type and level of aviation and community interest in the civil use of a current or former military airport.

(8) One copy of the FAA-approved ALP for each copy of the application. The ALP or supporting information must clearly show capacity and conversion related projects. Other information such as project costs, schedule, project justification, other maps and drawings showing the project locations, and any other supporting documentation that would make the application easier to understand should also be included. You may also provide photos, which would further describe the airport, projects, and otherwise clarify certain aspects of this application. These maps and ALPs should be cross-referenced with the project costs and project descriptions.

Redesignation of Airports Previously Designated and Applying for up to an Additional Five Years in the Program

Airports applying for redesignation to the MAP must submit the same information required by new candidate airports applying for a new designation. On the SF 424, Application for Federal Assistance, prescribed by the Office of Management and Budget Circular A–102, airports must indicate their application is for redesignation to the MAP. In addition to the information required for new candidates, airports requesting redesignation must also explain:

(1) Why a redesignation and additional MAP eligible project funding is needed to accomplish the conversion to meet the civilian role of the airport and the preferred time period for redesignation (not to exceed five years);

(2) Why funding of eligible work under other categories of AIP or other sources of funding would not accomplish the development needs of the airport; and

(3) Why, based on the previously funded MAP projects, the projects and/or funding levels were insufficient to accomplish the airport conversion needs and development goals.

In addition to the information requested above, airports applying for redesignation must provide a reanalysis of their original business/marketing plans (for example, a plan previously funded by the Office of Economic Adjustment or the original Master Plan

for the airport) and prepare a report. If there is not an existing business/marketing plan a business/marketing plan or strategy must be developed. The report must contain:

(1) Whether the original business/marketing plan is still appropriate;

(2) Is the airport continuing to work towards the goals established in the business/marketing plan;

(3) Discuss how the MAP projects contained in the application contribute to the goals of the sponsor and their plans; and

(4) If the business/marketing plan no longer applies to the current goals of the airport, how has the airport altered the business/marketing plan to establish a new direction for the facility and how do the projects contained in the MAP application aid in the completion of the new direction and goals and by what date does the sponsor anticipate graduating from the MAP.

This notice is issued pursuant to Title 49 U.S.C. 47118.

Issued at Washington, DC, on November 14, 2016.

Elliott Black,

Director, Office of Airport Planning and Programming.

[FR Doc. 2016–29318 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2016 0121]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel BLOOMS; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 6, 2017.

ADDRESSES: Comments should refer to docket number MARAD–2016–0121. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel BLOOMS is:

Intended Commercial Use of Vessel: ''6 or less passengers for hire''.

Geographic Region: Florida.

The complete application is given in DOT docket MARAD–2016–0121 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: November 28, 2016.

Gabriel Chavez,

Acting Secretary, Maritime Administration.

[FR Doc. 2016–29308 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0051]

Request for Comments on a New Information Collection

AGENCY: National Highway Traffic Safety Administration (NHTSA)

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on April 29, 2016 (Volume 81, Number 83, pages 25759–25760).

DATES: Comments must be submitted on or before January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Margaret Petrella, Volpe National Transportation Systems Center, U.S. Department of Transportation, 55 Broadway, Cambridge, MA 02142, 617–494–3582. Her email address is *margaret.petrella@dot.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number:

Title: Using Automated License Plate Readers for Traffic Safety Purposes.

Type of Request: Regular—New Information Collection.

Respondents: The information collection will interview law enforcement agency personnel from 12 agencies in the United States that use automated license plate readers for traffic safety purposes.

Estimated Number of Respondents: The estimated number of respondents for this information collection is 24 personnel. While there will be interview requests of approximately 48 personnel (4 personnel from each of 12 law enforcement agencies), the expected participation rate is 50%.

*Annual Time per Resp*onse: We estimate that it will take 40 minutes per respondent to complete each interview. This includes any time required to retrieve information.

Total Estimated Annual Burden Hours: 32 hours.

Frequency of Collection: One time only.

Abstract: NHTSA's interest in the state and practice of using ALPR for traffic safety purposes is in support of its mission, which is to save lives,

prevent injuries, and reduce economic costs due to road traffic crashes, through education, research, safety standards, and enforcement activity. NHTSA has statutory authority (*see* 23 U.S.C. 403; 49 CFR 1.50; 49 CFR part 501) to accomplish this mission. Under the Highway Safety Act of 1966, Section 403, the Secretary of Transportation is required to carry out research and demonstration programs. In addition, MAP–21, Subsection 402(c), states that the Secretary, acting through the NHTSA Administrator, shall establish a cooperative program to research and evaluate State highway safety countermeasures, such as use of ALPR. MAP–21 provides that this new cooperative research and evaluation program, the *National Cooperative Research and Evaluation Program* (*NCREP*), is to be administered by NHTSA and jointly managed by NHTSA and the Governors Highway Safety Association (GHSA). The U.S DOT Volpe National Transportation Systems Center is providing support to NHTSA in establishing and managing this new cooperative Program.

The information collection activity will be in 12 law enforcement agency (LEA) sites. Site selection will cover the diversity of LEAs that are deploying ALPR for traffic safety purposes, as determined through a thorough review of the literature. Case studies will involve interviews with a variety of personnel in each selected LEA. This approach will provide a knowledge base about this particular use of ALPR systems by providing rich, contextual information from those most knowledgeable about the weaknesses and strengths or incentives and barriers to this technology's effective implementation and use for traffic safety purposes.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Officer for the Office of the Secretary of Transportation, 725 17th Street NW., Washington, DC 20503.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department'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 collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Dated: December 2, 2016.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2016–29325 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0104; Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming Model Year 2013 and 2014 Ferrari F12 Berlinetta Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that model year (MY) 2013 and 2014 Ferrari F12 Berlinetta passenger cars (PCs) that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS), are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for sale in the United States and certified by their manufacturer as complying with the safety standards (the U.S.-certified version of the MY 2013 and 2014 Ferrari F12 Berlinetta PC), and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is January 6, 2017.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://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., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Instructions: Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

How to Read Comments Submitted to the Docket: You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at *https://www.regulations.gov.* Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

FOR FURTHER INFORMATION CONTACT: George Stevens, Office of Vehicle Safety Compliance, NHTSA (202–366–5308).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with

NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

G&K Automotive Conversion, Inc. (G&K) of Santa Ana, California (Registered Importer R–90–007) has petitioned NHTSA to decide whether nonconforming MY 2013 and 2014 Ferrari F12 Berlinetta PCs are eligible for importation into the United States. The vehicles which G&K believes are substantially similar are MY 2013 and 2014 Ferrari F12 Berlinetta PCs sold in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it compared non-U.S. certified MY 2013 and 2014 Ferrari F12 Berlinetta PCs to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

G&K submitted information with its petition intended to demonstrate that non-U.S. certified MY 2013 and 2014 Ferrari F12 Berlinetta PCs, as originally manufactured, conform to many applicable FMVSS in the same manner as their U.S.-certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that the non U.S.-certified MY 2013 and 2014 Ferrari F12 Berlinetta PCs, as originally manufactured, conform to: Standard Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect,* 103 *Windshield Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 106 *Brake Hoses,* 113 *Hood Latch System,* 116 *Motor Vehicle Brake Fluids,* 118 *Power-Operated Window, Partition, and Roof panel System,* 124 *Accelerator Control Systems,* 135 *Light Vehicle Brake Systems,* 139 *New Pneumatic Radial Tires for Light Vehicles,* 201 *Occupant Protection in Interior Impact,* 202a *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Mounting,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* and 302 *Flammability of Interior Materials.*

The petitioner also contends that the subject non-U.S certified vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* The speedometer and associated software must be modified to indicate vehicle speed in miles per hour (MPH).

Inspection of all vehicles and modification of any vehicles that fail to have all required displays and indicators function as required by the standard such that they comply with the standard.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* Installation of front and rear side marker lamps with U.S.-conforming components.

Inspection of all vehicles and installation of U.S.-model headlamps on vehicles not already so equipped to ensure that the vehicles meet the requirements of this standard.

Standard No. 110 *Tire Selection and Rims:* Installation of the required tire information placard.

Standard No. 111 *Rearview Mirrors:* Inscription of the required warning statement on the face of the passenger side rearview mirror.

Standard No. 114 *Theft Protection:* Program the warning system to be activated when the key is left in the locking device and the driver's door is open to comply with the requirements of this standard.

Standard No. 138 *Tire Pressure Monitoring Systems:* Inspect each vehicle to make sure the TPMS system has the [same] required functions as the U.S.-companion model.

Standard No. 208 *Occupant Crash Protection:* The passenger side air bag control system must be reprogramed so that the advanced air bag system function is identical to the U.S.-companion model.

Standard No. 214 *Side Impact Protection:* Verify the door beams on every incoming vehicle are original.

Standard No. 401 *Interior Trunk Release:* Installation of a U.S.-model interior trunk release system.

Standard No. 225 *Child Restraint Anchorage Systems:* Installation of a U.S. model child restraint anchorage system.

Standard No. 301 *Fuel System Integrity:* All vehicles must be inspected and any non U.S.-model fuel system components must be replaced with U.S.-model components to meet the requirements of the standard.

The petitioner additionally states that a vehicle identification plate must be affixed to the vehicle near the left windshield pillar to meet the requirements of 49 CFR part 565.

Because the subject petition covers nonconforming vehicles that have been manufactured on or after September 1, 2006, compliance with the advanced air bag requirements of FMVSS No. 208 is of significant concern to the agency. NHTSA is therefore particularly interested in comments regarding the ability of a Registered Importer to readily alter the subject vehicles to fully meet the driver and front outboard passenger frontal crash protection and child passenger protection requirements of FMVSS No. 208. The following is a partial listing of the components that may be affected:

a. Driver's frontal air bag module

b. Passenger frontal air bag module

c. Passenger frontal air bag cover

d. Knee air bags

e. Knee bolsters

f. Passenger outboard frontal seat belt system

g. Driver and front outboard seat assemblies including seat tracks and internal seat components

h. Steering wheel components, including the clock spring assembly, the steering column, and all connecting components

i. Instrument panel

j. Instrument panel support structure (*i.e.* cross beam)

k. Occupant sensing and classification systems, including sensors and processors

l. Restraint control modules

m. Passenger air bag status indicator light system, including related display components and wiring

n. Wiring harnesses between the restraint control module, occupant classification system and restraint system components

o. Control system computer software and firmware.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A), (a)(1)(B), and (b)(1); 49 CFR 593.7; delegation of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–29268 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2016–0121]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before February 6, 2017.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2016–0121 using any of the following methods:

Electronic submissions: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1–202–493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Brian Chodrow, Office of Safety Programs (NPD–210), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W44–230, Washington, DC 20590. Mr. Chodrow's phone number is 202–366–9765 and his email address is *Brian.Chodrow@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) 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;

(ii) 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;

(iii) how to enhance the quality, utility, and clarity of the information to be collected; and

(iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Education on Proper Use of Safety Belts on School Buses.

Type of Request: New information collection requirement.

OMB Clearance Number: None.

Form Number: None.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) proposes to conduct discussions and informal interviews to identify school districts who have implemented seat belts on school buses, and to gather information to understand the states' and local agencies' decisions to implement seat belts on school buses and the funding mechanisms that are used to pay for seat belt installation. These discussions will be held via telephone, email, and/or in-person throughout the course of the project. The findings will be used to develop a model policy and a best practices guide to assist jurisdictions that are considering the use of seat belts on school buses.

NHTSA also proposes to conduct a web-based survey to gather information about bus driver distraction as related to student behavior and seat belt use to see if the use of seat belts has influenced disruptive behavior. NHTSA expects to distribute the survey to at least one bus driver in each of the school districts that participate in the aforementioned interviews, but hopes to collect surveys from more than one driver in each of those school districts. The survey will not take more than 10–15 minutes to complete. Follow-up telephone discussions may also be conducted depending on the interest of respondents in providing additional information.

Description of the Need for the Information and Proposed Use of the Information—On average, from 2004–2013, each year eight (8) school-age pedestrians killed were struck by school transportation vehicles (school buses and non-school-bus vehicles used as school buses), and 4 by other vehicles involved in school-bus-related crashes. During this same time period, on average each year six school age children are killed in collisions while riding in a school bus. By focusing on safety both in and around the school bus, we could envision a future where there are zero school transportation fatalities.

There has generally been resistance against installing seat belts on school buses based on a variety of reasons including the existing safety features of school buses compared to other vehicles (*i.e.* taller and heavier vehicles, padded and high seat backs, etc.), need for drivers or aides to enforce wearing seat belts, cost, and other factors. However, it is commonly known that the use of seat belts has improved safety for other types of vehicles. Thus, on November 8, 2015, NHTSA Administrator Dr. Mark Rosekind stated, ''NHTSA has not always spoken with a clear voice on the issue of seat belts on school buses. So let me clear up any ambiguity now: The position of the National Highway Traffic Safety Administration is that seat belts save lives. That is true whether in a passenger car or in a big yellow bus. And saving lives is what we are about. So NHTSA's policy is that every child on every school bus should have a three-point seat belt. NHTSA will seek to use all the tools at our disposal to help achieve that goal, and today I want

to launch a nationwide effort to get us there.''

The current project seeks to understand the decisions that states and local agencies use when deciding to implement seat belts on school buses and the funding mechanisms that are used to pay for seat belt installation. From there, model policy and a best practices guide will be developed to assist jurisdictions that are considering the use of seat belts on school buses. Finally, the project will also obtain data related to the role of distraction and whether seat belts aid in managing behavior on school buses. The project will culminate with a final report to explain the results and outcomes from the project's activities.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—The first step of this process is to identify school districts who have implemented, or are planning to implement, seat belts on their school buses. NHTSA will reach out to current partners and connections including contacts in the National Association of State Directors of Pupil Transportation Services (NASDPTS), the National Association of Pupil Transportation (NAPT), the National School Transportation Association (NSTA), American School Bus Council (ASBC), school bus manufacturers and dealers, as well as any existing contacts in transportation departments, in order to help identify school districts. NHTSA anticipates contacting approximately 100 individuals across the country to ask general questions related to seat belt use in their jurisdictions. NHTSA will hold general discussions with these partners and contacts via telephone, email, and/or in person. As the goal of these conversations is to identify school districts that have implemented, or are considering implementing, seat belts on school buses, it is expected that these conversations will take no longer than 5 minutes. To the extent possible, NHTSA will also identify, in coordination with their partners, an appropriate contact(s) in each school district.

The next step, after school districts have been identified, is to reach out to these school districts who have agreed to provide NHTSA with more information and to gather information to understand the states' and local agencies' decisions to implement seat belts on school buses and the funding mechanisms that are used to pay for seat belt installation. Informational interviews will be conducted with State directors of pupil transportation and local school district professionals to identify policy components that influence seat belt acquisition and use. Prior to reaching out to any of the school districts, NHTSA will contact the NHTSA Regional Administrators to inform them of the school districts that NHTSA (through their contractor) intends to contact within their region. The process will then commence with introduction emails that NHTSA will send to the identified contact in each school district. The email will provide a brief overview of the project and discussion/interview goals, and will contain two attachments: (1) An introduction letter from NHTSA describing the goals of the project and interview process, and explaining how the information that they provide will be incorporated into the project and report, and (2) a list of discussion topics and questions. Although specific interview questions will be developed to keep the discussion on track as needed, it is expected that the actual interviews will occur as more of a fluid, conversational dialogue rather than a structured interview. NHTSA will follow up with each contact via telephone within 1–2 weeks of sending the email. During this call, NHTSA (through their contractor) will either work with the contact to schedule a time to conduct the interview, or will conduct the interview on the spot if preferred by the contact. In some cases, the necessary information may be retrieved through a one-time telephone or in-person discussion, while in other cases discussions may continue via telephone and email as an on-going discussion throughout the course of the project as school districts think of more information to provide or if they provide additional contacts to follow up with in their district. NHTSA is seeking to gather as much information as the school districts are willing to provide, and frequency of response and discussion will be driven by how involved the school district would like to be in the conversation. It is anticipated that the more detailed discussions will be held with approximately 25 individuals for a collective total of 100 hours, or an average of 4 hours per individual over an extended period.

Finally, NHTSA will conduct a survey to gather information about bus driver distraction as related to student behavior and seat belt use to see if the use of seat belts has influenced disruptive behavior. The potential respondents would include bus drivers from school districts who have implemented seat belts. The survey will be web-based and should take no longer than 10–15 minutes to complete. NHTSA expects to distribute the survey to at least one bus driver in each of the school districts that participate in the aforementioned interviews, but hopes to collect surveys from more than one driver in each of those school districts. NHTSA will share the link to the survey with their existing contact(s) within that school district, and will request that they distribute the survey to the appropriate bus drivers within their school district. Follow-up discussions may also be conducted via telephone or email depending on the interest of respondents in providing additional information that may not have been captured by the survey.

Throughout the project, the privacy of all participants will be protected. The Model Policy and Best Practices Guide, or any other reports developed as a result of this data collection effort, will not identify any individuals by name. School districts may be identified, but only if permission is given to NHTSA by the school district. Additionally, any school district identified in the Model Policy and Best Practices will be given the opportunity to review and edit any text referring directly to their school district.

The online bus driver survey results will be password protected and access will only be given to team members who have been authorized by the Project Manager (principal investigators and research assistants). The survey data will be exported to an Excel® file and stored in a SharePoint site folder that is also only visible to those who have been authorized by the Project Manager. The research team will check the data file as soon as it is exported to the secure SharePoint folder to ensure that no personally identifiable information (*e.g.* bus driver name or email address) is included. Though survey respondents will be asked to indicate their school district, they will not be required to provide their name or contact information unless they wish to provide additional information to the project team. Any personally identifiable information that is provided will be kept separate from the data collected.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information—NHTSA estimates that the total respondent burden for this data collection would be 133.3 hours.

The initial discussions would take approximately 5 minutes with 100 people for a total of 8.3 hours. The detailed discussions with school districts who have agreed to participate with the project will take place with a commitment of an average of 4 hours with 25 people for a total of 100 hours.

The bus driver survey would take 15 minutes with approximately 100 people for a total of 25 hours.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Dated: December 2, 2016.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2016–29320 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2016–0136]

Pipeline Safety: Meeting of the Gas Pipeline Safety Advisory Committee

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice; Advisory Committee meeting reschedule.

SUMMARY: This notice announces that the public meeting of the Technical Pipeline Safety Standards Committee, also known as the Gas Pipeline Advisory Committee (GPAC), scheduled for December 7–8, 2016, has been rescheduled for January 11–12, 2017. Notice of the original meeting appeared in the **Federal Register** on November 22, 2016, (81 FR 83795).

DATES: The postponed meeting was scheduled for 8:30 a.m. to 5:00 p.m. EST on both December 7, 2016, and December 8, 2016. The rescheduled meeting will take place from 8:30 a.m. to 5:00 p.m. on both January 11, 2017, and January 12, 2017.

The meetings will not be web cast; however, presentations will be available on the meeting Web site and posted on the E-Gov Web site: *http://www.regulations.gov* under docket number PHMSA–2016–0136 within 30 days following the meeting.

ADDRESSES: The meeting will be held at the Hilton Arlington, 950 North Stafford Street, Arlington, VA, 22203. Additional information regarding hotel and meeting registration and the agenda will be published on the following pipeline advisory committee meeting and registration page: *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=121.*

Public Participation

This meeting will be open to the public. Members of the public who wish to attend in person are asked to register at: *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=121* no later than January 4, 2017, in order to facilitate entry and guarantee seating. Members of the public who attend in person will also be provided opportunities to make statements during the meeting.

Written comments: Persons who wish to submit written comments on the meeting may be submitted to the docket in the following ways:

E-Gov Web site: http://www.regulations.gov. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.

Fax: 1–202–493–2251.

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

Hand Delivery: Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on Federal holidays.

Instructions: Identify the docket number PHMSA–2016–0136 at the beginning of your comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, consider reviewing DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (65 FR 19477) or view the Privacy Notice at *http://www.regulations.gov* before submitting any such comments.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on PHMSA–2016- 0136.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail.

Privacy Act Statement

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.*

Services for Individuals with Disabilities: The public meeting will be physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Cheryl Whetsel at *cheryl.whetsel@dot.gov* by December 30, 2016.

FOR FURTHER INFORMATION CONTACT: For information about the meeting, contact Cheryl Whetsel by phone at 202–366–4431 or by email at *cheryl.whetsel@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Meeting Details and Agenda

The GPAC will be discussing the proposed rule, ''Safety of Gas Transmission and Gathering Pipelines'' published in the **Federal Register** on April 8, 2016, (81 FR 20722), and the associated regulatory analysis. PHMSA is proposing changes to part 192 that include:

- Requiring periodic assessments of pipelines in locations where persons are expected to be at risk that are not already covered under the integrity management program requirements;
- Modifying the repair criteria, both inside and outside of high consequence areas;
- Requiring inspections of pipelines in areas affected by extreme weather, man-made and natural disasters, and other similar events;
- Providing additional specificity for in-line inspection, including explicit requirements to account for uncertainty of reported inspection data when evaluating in-line inspection data to identify anomalies;
- Expanding integrity assessment methods to explicitly address guided wave ultrasonic inspection and excavation with direct in-situ examination;
- Providing clearer functional requirements for conducting risk assessment for integrity management, including addressing seismic risk;
- Expanding the mandatory data collection and integration requirements for integrity management, including data validation and seismicity;
- Adding requirements to address Management of Change;
- Repealing the use of API 80 for gathering lines;
- Applying Type B requirements to newly regulated Type A gathering lines

in Class 1 locations to > 8-inch along with emergency requirements (GAO Recommendation 14–667);

• Extending the reporting requirements to all gathering lines;

• Expanding requirements for corrosion protection to specify additional post-construction quality checks and periodic operational and maintenance checks to address coating integrity, cathodic protection, and gas quality monitoring;

• Requiring operators to report MAOP Exceedance;

• Requiring safety features on in-line inspection tool launchers and receivers;

• Adding certain types of roadways to definition of ''identified sites'' (NTSB P–14–1); and

• Addressing grandfathered pipe and pipe with inadequate records.

The agenda, once finalized, will be published on the meeting page.

II. Committee Background

The GPAC is a statutorily mandated advisory committee that advises PHMSA on proposed gas pipeline safety standards and risk assessments for transporting gas and for gas pipeline facilities. The committee is established in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, as amended) and 49 U.S.C. 60115. The committee consists of 15 members—with membership evenly divided among the federal and state governments, the regulated industry, and the general public. The committees advise PHMSA on the technical feasibility, reasonableness, cost-effectiveness, and practicability of each proposed pipeline safety standard.

Issued in Washington, DC on December 2, 2016, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Acting Associate Administrator for Pipeline Safety.

[FR Doc. 2016–29360 Filed 12–6–16; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Orders (E.O.s) 13722, 13687, and 13382

AGENCY: Office of Foreign Assets Control, Treasury

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing the names of 14 entities whose property and interests in property are blocked pursuant to E.O. 13722, ''Blocking Property of the Government of North Korea and the Workers' Party of Korea, and Prohibiting Certain Transactions With Respect to North Korea,'' 16 aircraft identified as property in which a Specially Designated National has an interest and that are therefore blocked pursuant to E.O. 13722, four individuals and one entity whose property and interests in property are blocked pursuant to E.O. 13687, ''Imposing Additional Sanctions With Respect to North Korea,'' and three individuals and one entity whose property and interests in property are blocked pursuant to E.O. 13382, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters.''

DATES: OFAC's actions described in this notice were effective on December 2, 2016.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's OFAC: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On December 2, 2016, OFAC blocked the property and interests in property of the following 14 entities pursuant to E.O. 13722, ''Blocking Property of the Government of North Korea and the Workers' Party of Korea, and Prohibiting Certain Transactions With Respect to North Korea'':

Entities

1. AIR KORYO (a.k.a. AIRKORYO), Sunan District, Pyongyang, Korea, North; Swissotel, Hongkong-Macau Center, Dong Si Shi Tiao Li Jiao Qiao, Beijing 10027, China; Chilbosan Hotel, No 81, Shyiwei Road, Heping District, Shenyang, China; Room 412, XinHui Bldg, No 1197 Rd Husong, District SongJiang, Shanghai, China; Soon Vijai Conominun, Room 208, Floor 2, New Petchburi Road, Khwaeng Bangkapi, Huai Khwang, Bangkok 10310, Thailand; Airport, 45, Portovaya Street, Artyom, Primorski Krai 692760, Russia; Mosfilimovskaya 72, Moscow 101000, Russia; Friedrichstr 106B, Berlin 10117, Germany; 20–114, Level 20, Menara Safuan, No.80, Jalan Ampang, Kuala Lumpur 50450, Malaysia; Office 10, 2nd floor, Mghateer complex 31, Block 40, Al Farwaniyah, Kuwait [DPRK3].
2. KOREA NATIONAL INSURANCE CORPORATION (a.k.a. KOREA FOREIGN INSURANCE COMPANY; a.k.a. KOREA NATIONAL INSURANCE COMPANY), Central District, Pyongyang, Korea, North [DPRK3].
3. KOREA OIL EXPLORATION CORPORATION (a.k.a. CHOSUN OIL EXPLORATION COMPANY; a.k.a. KOREA OIL EXPLORATION COMPANY; a.k.a. ''KOEC''), Ulam Dong, Taedonggang District, Pyongyang, Korea, North [DPRK3].
4. MANSUDAE OVERSEAS PROJECT GROUP OF COMPANIES (a.k.a. MANSUDAE ART STUDIO), Pyongyang, Korea, North [DPRK3].
5. KOREA GENERAL CORPORATION FOR EXTERNAL CONSTRUCTION, Korea, North [DPRK3].
6. KOREA RUNGRADO GENERAL TRADING CORPORATION (a.k.a. RUNGRADO TRADE COMPANY), Korea, North [DPRK3].
7. NAMGANG CONSTRUCTION, Korea, North [DPRK3].
8. DAEWON INDUSTRIES (a.k.a. DAEWON INDUSTRY COMPANY; a.k.a. TAEWO'N INDUSTRIES), Pyongyang, Korea, North [DPRK3].
9. KANGBONG TRADING CORPORATION, Korea, North [DPRK3].
10. KORYO BANK, Koryo Bank Building, Pulgun Street, Pyongyang, Korea, North; SWIFT/BIC KORBKPPY; all offices worldwide [DPRK3].
11. KORYO CREDIT DEVELOPMENT BANK (a.k.a. KORYO GLOBAL CREDIT BANK; a.k.a. KORYO GLOBAL TRUST BANK), Yanggakdo International Hotel, RYUS, Pyongyang, Korea, North; SWIFT/BIC KGCBKPPY; all offices worldwide [DPRK3].
12. KUMGANG BANK, Kumgang Bank Building, Jungsong-don, Pyongyang, Korea, North; SWIFT/BIC KMBKKPPY; all offices worldwide [DPRK3].
13. NORTH EAST ASIA BANK, Haebangsan-dong, Central District, Pyongyang, Korea, North; SWIFT/BIC NEABKPPY; all offices worldwide [DPRK3].

14. RASON INTERNATIONAL COMMERCIAL BANK, Rason, Korea, North; all offices worldwide [DPRK3].

In addition, on December 2, 2016, OFAC identified the following 16 aircraft as blocked pursuant to E.O. 13722, ''Blocking Property of the Government of North Korea and the Workers' Party of Korea, and Prohibiting Certain Transactions With Respect to North Korea'':

Aircraft

1. P–532; Aircraft Manufacture Date 1974; Aircraft Model AN24–RV; Aircraft Operator Air Koryo (aircraft) [DPRK3].
2. P–533; Aircraft Manufacture Date 1974; Aircraft Model AN24–RV; Aircraft Operator Air Koryo (aircraft) [DPRK3].
3. P–537; Aircraft Manufacture Date 1966; Aircraft Model AN24–B; Aircraft Operator Air Koryo (aircraft) [DPRK3].
4. P–552; Aircraft Manufacture Date 1976; Aircraft Model T154–B; Aircraft Operator Air Koryo (aircraft) [DPRK3].
5. P–561; Aircraft Manufacture Date 1983; Aircraft Model T154–B; Aircraft Operator Air Koryo (aircraft) [DPRK3].
6. P–632; Aircraft Manufacture Date 1994; Aircraft Model T204–300; Aircraft Operator Air Koryo (aircraft) [DPRK3].
7. P–633; Aircraft Manufacture Date 2009; Aircraft Model T204–100; Aircraft Operator Air Koryo (aircraft) [DPRK3].
8. P–671; Aircraft Manufacture Date 2012; Aircraft Model A148–100; Aircraft Operator Air Koryo (aircraft) [DPRK3].
9. P–672; Aircraft Manufacture Date 2015; Aircraft Model A148–100; Aircraft Operator Air Koryo (aircraft) [DPRK3].
10. P–813; Aircraft Manufacture Date 1983; Aircraft Model T134–B; Aircraft Operator Air Koryo (aircraft) [DPRK3].
11. P–835; Aircraft Manufacture Date 1969; Aircraft Model IL18–D; Aircraft Operator Air Koryo (aircraft) [DPRK3].
12. P–881; Aircraft Manufacture Date 1986; Aircraft Model IL62–M; Aircraft Operator Air Koryo (aircraft) [DPRK3].
13. P–885; Aircraft Manufacture Date 1979; Aircraft Model IL62–M; Aircraft Operator Air Koryo (aircraft) [DPRK3].
14. P–912; Aircraft Manufacture Date 1990; Aircraft Model IL76–TD; Aircraft Operator Air Koryo (aircraft) [DPRK3].
15. P–913; Aircraft Manufacture Date 1990; Aircraft Model IL76–TD; Aircraft Operator Air Koryo (aircraft) [DPRK3].
16. P–914; Aircraft Manufacture Date 1990; Aircraft Model IL76–TD; Aircraft Operator Air Koryo (aircraft) [DPRK3].

In addition, on December 2, 2016, OFAC blocked the property and interests in property of the following four individuals and one entity whose property and interests in property are blocked pursuant to E.O. 13687, ''Imposing Additional Sanctions With Respect to North Korea'':

Individuals

1. HUSSAIN, Mavungal; DOB 03 Jun 1961 (individual) [DPRK2] (Linked To: KOREA MINING DEVELOPMENT TRADING CORPORATION).
2. CHANG, Chang-ha (a.k.a. JANG, Chang Ha); DOB 10 Jan 1964; President of Second Academy of Natural Sciences (individual) [DPRK2] (Linked To: SECOND ACADEMY OF NATURAL SCIENCES).
3. CHANG, Kyong-hwa (a.k.a. JANG, Kyong Hwa); DOB 13 Nov 1951; Official at Second Academy of Natural Sciences (individual) [DPRK2] (Linked To: SECOND ACADEMY OF NATURAL SCIENCES).
4. CHO, Chun-ryong (a.k.a. JO, Chun Ryong); DOB 04 Apr 1960; Chairman of the Second Economic Committee (individual) [DPRK2] (Linked To: SECOND ECONOMIC COMMITTEE).

Entity

1. KOREA HAEGUMGANG TRADING CORPORATION (a.k.a. HAEGU'MGANG TRADING COMPANY; a.k.a. KOREA RIMYONGSU TRADING CORPORATION; a.k.a. NAEGU'NGANG TRADING COMPANY), Korea, North [DPRK2].

In addition, on December 2, 2016, OFAC blocked the property and interests in property of the following three individuals and one entity whose property and interests in property are blocked pursuant to E.O. 13382, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters'':

Individuals

1. KIM, Chol Nam, Korea, North; DOB 19 Feb 1970; Passport 563120238 (Korea, North); President of Korea Kumsan Trading Corporation (individual) [NPWMD] (Linked To: KOREA KUMSAN TRADING CORPORATION).
2. PAK, Han Se (a.k.a. KANG, Myong Chol), Korea, North; Passport 290410121 (Korea, North); Vice Chairman of the Second Economic Committee (individual) [NPWMD] (Linked To: SECOND ECONOMIC COMMITTEE).
3. KIM, Se Gon; DOB 13 Nov 1969; Passport 472310104 (Korea, North); Representative of Ministry of Atomic Energy Industry (individual) [NPWMD] (Linked To: MINISTRY OF ATOMIC ENERGY INDUSTRY).

Entity

1. KOREA KUMSAN TRADING CORPORATION, Pyongyang, Korea, North [NPWMD] (Linked To: GENERAL BUREAU OF ATOMIC ENERGY).

Dated: December 2, 2016.

John Battle,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–29311 Filed 12–6–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

Funding Availability Under Supportive Services for Veteran Families Program

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice of funding availability.

SUMMARY: Funding Opportunity Title: Supportive Services for Veteran Families Program; Announcement Type: Initial; Funding Opportunity Number: VA–SSVF–120516; Catalog of Federal Domestic Assistance Number: 64.033, VA Supportive Services for Veteran Families Program.

The Department of Veterans Affairs (VA) is announcing the availability of funds for supportive services grants under the Supportive Services for Veteran Families (SSVF) program. This Notice of Fund Availability (NOFA) contains information concerning the SSVF program, initial and renewal supportive services grant application processes, and the amount of funding available. Awards made for supportive services grants will fund operations beginning October 1, 2017.

DATES: Applications for supportive services grants under the SSVF Program must be received by the SSVF Program Office by 4:00 p.m. Eastern Standard Time on February 3, 2017. In the

interest of fairness to all competing applicants, this deadline is firm as to date and hour, and VA will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays, computer service outages, or other delivery-related problems.

ADDRESSES: *For a Copy of the Application Package:* Copies of the application can be downloaded from the SSVF Web site at: *www.va.gov/homeless/ssvf.asp.* Questions should be referred to the SSVF program Office via email at *SSVF@va.gov.* For detailed SSVF program information and requirements, see part 62 of title 38, Code of Federal Regulations (38 CFR part 62).

Submission of Application Package: Applicants are strongly encouraged to submit applications electronically following instructions found at: *www.va.gov/homeless/ssvf.asp.* Alternatively, applicants can mail in applications. If mailed, applicants must submit two completed, collated, hard copies of the application and two compact discs (CDs) containing electronic versions of the entire application. Each application copy must: (i) Be fastened with a binder clip, and (ii) contain tabs listing the major sections of and exhibits to the application. Each CD must be labeled with the applicant's name and must contain an electronic copy of the entire application. A budget template must be attached in Excel format on the CD, but all other application materials may be attached in a PDF or other format. The application copies and CDs must be submitted to the following address: Supportive Services for Veteran Families Program Office, National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201, Philadelphia, PA 19104. Applications may not be sent by facsimile (fax). Applications must be received in the SSVF Program Office by 4:00 p.m., Eastern Standard Time on the application deadline date. Applications must arrive as a complete package. Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected. See Section II.C. of this NOFA for maximum allowable grant amounts.

Technical Assistance: Information regarding how to obtain technical assistance with the preparation of an initial and/or renewal supportive services grant application is available on the SSVF Program Web site at *http://www.va.gov/HOMELESS/SSVF.asp.*

FOR FURTHER INFORMATION CONTACT: Mr. John Kuhn, National Director, Supportive Services for Veteran Families at the following email address: *SSVF@va.gov.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

A. Purpose: The SSVF program's purpose is to provide supportive services grants to private non-profit organizations and consumer cooperatives, who will coordinate or provide supportive services to very low-income Veteran families who: (i) Are residing in permanent housing; (ii) are homeless and scheduled to become residents of permanent housing within a specified time period; or (iii) after exiting permanent housing within a specified time period, are seeking other housing that is responsive to such very low-income Veteran family's needs and preferences. SSVF prioritizes the delivery of rapid re-housing services to homeless Veteran households. Rapid re-housing is an intervention designed to help individuals and families exit homelessness, return to housing in the community, and avoid homelessness again in the near term. The core components of a rapid re-housing program are housing identification, move-in and rent assistance, and rapid re-housing case management and services. These core components represent the minimum that a program must be providing to households to be considered a rapid re-housing program, but do not provide guidance for what constitutes an effective rapid re-housing program. Applicants should familiarize themselves with the Rapid Re-housing Performance Benchmarks and Program Standards found on VA's SSVF Web site at: *www.va.gov/homeless/ssvf/index.asp.*

B. Funding Priorities: The principle goal for this NOFA is to provide support to those applicants who demonstrate the greatest capacity to end homelessness among Veterans or, sustain the gains made in ending homelessness among Veterans in communities that have already met United States Interagency Council on Homelessness (USICH) Federal Criteria and Benchmarks. Priority will be given to grantees who can demonstrate adoption of evidence-based practices in their application. Under Priority 1, VA will provide funding to those grantees with 3-year accreditation from the Commission on Accreditation of Rehabilitation Facilities (CARF) in Employment and Community Services: Rapid Rehousing and Homeless Prevention standards, a 4-year accreditation from the Council on Accreditation's (COA) accreditation in Supported Community Living Services standards, or a 3-year accreditation in The Joint Commission's (JC) Behavioral Health Care: Housing Support Services Standards. Priority 2 includes existing grantees seeking to renew their grants. Applicants eligible for Priority 2 funding include those grantees with 3-year awards who expect to have expended all of their funding sometime in fiscal year (FY) 2017 or FY 2018. [Note: This applies only to 3-year awards not associated with CARF, COA, or JC accreditation. Grantees with 3-year awards due to CARF, COA, or JC accreditation would apply as Priority 1.] For grantees with 3-year awards that will exhaust funds during FY 2018, awards will be pro-rated based on the number of months needed to continue services through the end of FY 2018. Priority 3 applications will be accepted from new applicants in the communities described in Section II.B. Funds remaining after Priority 1 awards will be allocated to Priority 2 and 3 applicants based on available funding.

C. Definitions: Part 62 of title 38, Code of Federal Regulations (38 CFR part 62), contains definitions of terms used in the SSVF program.

D. Approach: Respondents to this NOFA should base their proposals and applications on the current requirements of part 62 of title 38. Grantees will be expected to leverage supportive services grant funds to enhance the housing stability of very low-income Veteran families who are occupying permanent housing. In doing so, grantees are required to establish relationships with local community resources. Therefore, agencies must work through coordinated partnerships built either through formal agreements or the informal working relationships commonly found amongst successful social service providers. As part of the application, all applicants are strongly encouraged to provide letters of support from their respective VA Network Homeless Coordinator (or their designee). In addition, applicants are strongly encouraged to provide letters of support from the Continuum of Care (CoC) where they plan to deliver services that reflect the applicant's engagement in the CoC's efforts to coordinate services. The CoC may elect to provide VA with a rank order of their support in lieu of providing individual letters of support. A CoC is a community plan to organize and deliver housing and services to meet the needs of people who are homeless as they

move to stable housing and maximize self-sufficiency. It includes action steps to end homelessness and prevent a return to homelessness (CoC locations and contact information can be found at the Department of Housing and Urban Development's (HUD) Web site at *http://www.hudhre.info/index.cfm?do=viewCocMaps*). The CoC's letter of support should describe the applicant's participation in the CoC's coordinated assessment efforts (coordinated assessment refers to a common process for accessing homeless assistance services including: Prevention, diversion, emergency shelter, transitional housing, rapid re-housing, supportive services, and permanent supportive housing). In addition, any applicant proposing to serve an Indian Tribal area is strongly encouraged to provide a letter of support from the relevant Indian Tribal Government. The aim of the provision of supportive services is to assist very low-income Veteran families residing in permanent housing to remain stably housed and to rapidly transition those not currently in permanent housing to stable housing. SSVF emphasizes the placement of homeless Veteran families who are described in VA's regulations as (i) very low-income Veteran families who are homeless and scheduled to become residents of permanent housing within 90 days, and (ii) very low-income Veteran families who have exited permanent housing within the previous 90 days to seek other housing that is responsive to their needs and preferences. As a crisis intervention program, the SSVF program is not intended to provide long-term support for participants, nor will it be able to address all of the financial and supportive services needs of participants that affect housing stability. Rather, when participants require long-term support, grantees should focus on connecting such participants to income supports, such as employment and mainstream Federal and community resources (*e.g.,* HUD–VA Supportive Housing program, HUD Housing Choice Voucher programs, McKinney-Vento funded supportive housing programs, Temporary Assistance for Needy Families (TANF), Social Security Income/Social Security Disability Insurance (SSI/SSDI), etc.) that can provide ongoing support as required.

Assistance in obtaining or retaining permanent housing is a fundamental goal of the SSVF program. Grantees must provide case management services in accordance with 38 CFR 62.31. Such case management should include tenant counseling, mediation with landlords and outreach to landlords.

E. Authority: Funding available under this NOFA is authorized by 38 U.S.C. 2044. VA implements the SSVF program through regulations in 38 CFR part 62. Funds made available under this NOFA are subject to the requirements of these regulations and other applicable laws and regulations.

F. Requirements for the Use of Supportive Services Grant Funds: The applicant's request for funding must be consistent with the limitations and uses of supportive services grant funds set forth in 38 CFR part 62 and this NOFA. In accordance with the regulations and this NOFA, the following requirements apply to supportive services grants awarded under this NOFA:

1. Grantees may use a maximum of 10 percent of supportive services grant funds for administrative costs identified in 38 CFR 62.70.

2. Grantees must use a minimum of 60 percent of the temporary financial assistance portion of their supportive services grant funds to serve very low-income Veteran families who qualify under 38 CFR 62.11(b). (NOTE: Grantees may request a waiver to decrease this minimum, as discussed in section V.B.3.a.)

3. Grantees may use a maximum of 50 percent of supportive services grant funds to provide the supportive service of temporary financial assistance paid directly to a third party on behalf of a participant for child care, emergency housing assistance, transportation, rental assistance, utility-fee payment assistance, security deposits, utility deposits, moving costs, and general housing stability assistance (which includes emergency supplies) in accordance with 38 CFR 62.33 and 38 CFR 62.34.

G. Guidance for the Use of Supportive Services Grant Funds: Grantees are expected to demonstrate adoption of evidence-based practices most likely to lead to reductions in homelessness or, in communities that have successfully ended homelessness among Veterans (as defined by the USICH's Federal Criteria and Benchmarks or, alternatively, Community Solutions' Functional Zero), (the latter can be found at: *https://cmtysolutions.org/sites/default/files/final_zero_2016_metrics.pdf*), a capacity to sustain these gains. As part of their application, the applying organization's Executive Director must certify on behalf of the agency that they will actively participate in community planning efforts and operate the rapid re-housing component of their SSVF grant in a manner consistent with the Rapid Re-housing Performance Benchmarks and Program Standards found at *www.va.gov/homeless/ssvf/index.asp.* It is VA policy to support a ''Housing First'' model in addressing and ending homelessness. Housing First establishes housing stability as the primary intervention in working with homeless persons. The Housing First approach is based on research that shows that a homeless individual or household's first and primary need is to obtain stable housing, and that other issues that may affect the household can and should be addressed as housing is obtained. Research supports this approach as an effective means to end homelessness. Housing is not contingent on compliance with mandated therapies or services. Instead, participants must comply with a standard lease agreement and are provided with the services and supports that are necessary to help them do so successfully.

Grantees must develop plans that will ensure that Veteran participants have the level of income and economic stability needed to remain in permanent housing after the conclusion of the SSVF intervention. Both employment and benefits assistance from VA and non-VA sources represent a significant underutilized source of income stability for homeless Veterans. The complexity of program rules and the stigma some associate with entitlement programs contributes to their lack of use. For this reason, grantees are encouraged to consider strategies that can lead to prompt and successful access to employment and benefits that are essential to retaining housing.

1. Consistent with the Housing First model supported by VA, grantees are expected to offer the following supportive services: Counseling participants about housing; assisting participants in understanding leases; securing utilities; making moving arrangements; providing representative payee services concerning rent and utilities when needed; and mediation and outreach to property owners related to locating or retaining housing. Grantees may also assist participants by providing rental assistance, security or utility deposits, moving costs, emergency housing, or general housing stability assistance; or using other Federal resources, such as the HUD's ESG, or supportive services grant funds subject to the limitations described in this NOFA and 38 CFR 62.34.

2. As SSVF is a short-term crisis intervention, grantees must develop plans that will produce sufficient income to sustain Veteran participants in permanent housing after the conclusion of the SSVF intervention. Grantees must ensure the availability of

employment and vocational services either through the direct provision of these services or their availability through formal or informal service agreements. Agreements with Homeless Veteran Reintegration Programs funded by the U.S. Department of Labor are strongly encouraged. For participants unable to work due to disability, income must be established through available benefits programs.

3. Per 38 CFR 62.33, grantees must assist participants in obtaining public benefits. Grantees must screen all participants for eligibility for a broad range of entitlements such as TANF, Social Security, the Supplemental Nutrition Assistance Program (SNAP), the Low Income Home Energy Assistance Program (LIHEAP), the Earned Income Tax Credit (EITC), and local General Assistance programs. Grantees are expected to access the Substance Abuse and Mental Health Services Administration's SSI/SSDI Outreach, Access, and Recovery (SOAR) program either though community linkages or by training staff to deliver SOAR services. In addition, where available, grantees should access information technology tools to support case managers in their efforts to link participants to benefits.

4. Grantees are encouraged to provide, or assist participants in obtaining, legal services relevant to issues that interfere with the participants' ability to obtain or retain permanent housing. (NOTE: Information regarding legal services provided may be protected from being released to the grantee or VA under attorney-client privilege, although the grantee must provide sufficient information to demonstrate the frequency and type of service delivered.) Support for legal services can include paying for court filing fees to assist a participant with issues that interfere with the participant's ability to obtain or retain permanent housing or supportive services, including issues that affect the participant's employability and financial security. Grantees (in addition to employees and members of grantees) may represent participants before VA with respect to a claim for VA benefits, but only if they are recognized for that purpose pursuant to 38 U.S.C. Chapter 59. Further, the individual providing such representation must be accredited pursuant to 38 U.S.C. Chapter 59.

5. Access to mental health and addiction services are required by SSVF; however, grantees cannot fund these services directly through the SSVF grant. Therefore, applicants must demonstrate, through either formal or informal agreements, their ability to promote rapid access to and engagement with mental health and addiction services for the Veteran and family members.

6. VA recognizes that extremely low-income Veterans, with incomes below 30 percent of the area median income, face greater barriers to permanent housing placement. Grantees should consider how they can support these participants.

7. When serving participants who are residing in permanent housing, the defining question to ask is: ''Would this individual or family be homeless but for this assistance?'' The grantee must use a VA-approved screening tool with criteria that targets those most at-risk of homelessness. To qualify for SSVF services, a participant who is served under 38 CFR 62.11(a) (homeless prevention) must not have sufficient resources or support networks (*e.g.,* family, friends, faith-based or other social networks) immediately available to prevent them from becoming homeless. To further qualify for services under 38 CFR 62.11(a), the grantee must document that the participant:

(a) Has moved because of economic reasons two or more times during the 60 days immediately preceding the application for homelessness prevention assistance;

(b) Is living in the home of another because of economic hardship;

(c) Has been notified in writing that their right to occupy their current housing or living situation will be terminated within 21 days after the date of application for assistance;

(d) Lives in a hotel or motel and the cost of the hotel or motel stay is not paid by charitable organizations or by Federal, State, or local government programs for low-income individuals;

(e) Is exiting a publicly funded institution or system of care (such as a health care facility, a mental health facility, or correctional institution) without a stable housing plan; or

(f) Otherwise lives in housing that has characteristics associated with instability and an increased risk of homelessness, as identified in the recipient's approved screening tool.

8. SSVF grantees are required to participate in local planning efforts designed to end Veteran homelessness. Grantees may use grant funds to support SSVF involvement in such community planning by sub-contracting with CoCs, when such funding is essential to create or sustain the development of these data driven plans.

9. When other funds from community resources are not readily available to assist program participants, grantees may choose to utilize supportive services grants, to the extent described in this NOFA and in 38 CFR 62.33 and 62.34, to provide temporary financial assistance. Such assistance may, subject to the limitations in this NOFA and 38 CFR part 62, be paid directly to a third party on behalf of a participant for child care, transportation, family emergency housing assistance, rental assistance, utility-fee payment assistance, security or utility deposits, moving costs and general housing stability assistance as necessary.

II. Award Information

A. Overview: This NOFA announces the availability of funds for supportive services grants under the SSVF Program and pertains to proposals for renewal of existing supportive services grant programs and opportunities for new grants in targeted communities.

B. Funding: The following funding priorities for this NOFA are as follows.

1. *Priority 1.* Under Priority 1, VA will provide funding to those grantees with 3-year CARF, 4-year COA accreditations, or 3-year JC accreditations. Proof of accreditation must be submitted with the application no later than the application due date.

2. *Priority 2.* Priority 2 includes all other existing grantees seeking to renew their grants. Eligible applicants include those grantees with 3-year awards who expect to have expended all of their funding sometime in FY 2017 or FY 2018. [Note: This applies only to 3-year awards not associated with CARF, COA, or JC accreditation. Grantees with 3-year awards due to CARF, COA, or JC accreditation would apply as Priority 1.] For grantees with 3-year awards who will exhaust funds during FY 2018, awards will be pro-rated based on the numbers of months needed to continue funding through the end of FY 2018. Both Priority 1 and 2 applicants must apply using the renewal application. To be eligible for renewal of a supportive services grant, the Priority 1 and 2 applicants' program concept must be substantially the same as the program concept of the grantees' current grant award. Renewal applications can request funding that is equal to or less than their current annualized award. If sufficient funding is available, VA may provide an increase of up to 2 percent from the previous year's award. Any percentage increase, if provided, will be awarded uniformly to all grant recipients regardless of their grant award.

3. *Priority 3.* Priority 3 applications will be accepted from new grantees in the following targeted communities.

State	CoC	CoC ID
GA ...	Georgia Balance of State CoC.	GA–501
AZ ...	Phoenix/Mesa/Maricopa County Regional CoC.	AZ–502.
TX ...	Dallas City & County/Irving CoC.	TX–600.
CO ..	Colorado Balance of State CoC.	CO–500.
CA ...	Sacramento City & County CoC.	CA–503.
TX ...	Austin/Travis County CoC	TX–503.
HI	Hawaii Balance of State CoC.	HI–500.
CA ...	Santa Rosa/Petaluma/Sonoma County CoC.	CA–504.

Funds remaining after Priority 1 awards will be available to Priority 2 and 3 applicants.

As provided in section V.5., VA may in its discretion offer to award a non-renewed grant to the highest-ranked applicant that is awarded a renewal grant in the same community as, or a proximate community to, the non-renewed grant, so long as that applicant has the capacity to promptly begin providing services in connection with all awards. In such instance, the amount of the award will be equal to or less than the prior award which was not renewed.

C. Allocation of Funds: Funding will be awarded under this NOFA to existing grantees for a 1 to 3-year period beginning October 1, 2017. The following requirements apply to supportive services grants awarded under this NOFA:

1. In response to this NOFA, only existing grantees can apply as Priority 1 or 2 grantees.

2. New applications for Priority 3 will only be accepted from designated target communities and requests cannot exceed $2 million. Eligible entities can submit no more than one application for new funding.

3. Each renewal grant request cannot exceed the current annualized award.

4. Applicants may request an amount less than their current award. (This will not be considered a substantial change to the program concept.)

5. If a grantee failed to use all of awarded funds in the previous fiscal year (FY 2016) or had unspent funds returned to VA in FY 2017, VA may elect to limit renewal award to the amount of funds used in the previous fiscal year or in the current fiscal year less the money swept.

6. Applicants should fill out separate applications for each supportive services funding request.

D. Supportive Services Grant Award Period: Grant awards are generally made for a 1-year period, although selected grants may be eligible for a 3-year award (see VI.C.6). All grants are eligible to be renewed subject to the availability of funding.

III. Eligibility Information

A. Eligible Applicants: For Priority 1 and 2, only eligible entities that are existing grantees can apply in response to this NOFA. For Priority 3, any eligible entity may apply for new funding in one of the listed target communities. In order to be eligible, an applicant must qualify as a private non-profit organization (section 501(c)(3) or 501(c)(19) tax exempt status is required) or a consumer cooperative as defined in 38 U.S.C. 2044(f). In addition, tribally designated housing entities (as defined in section 4 of the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4103)) are eligible.

B. Cost Sharing or Matching: None.

IV. Application and Submission Information

A. Obtaining an Application Package: Applications can be downloaded from VA's SSVF Web site at: *www.va.gov/homeless/ssvf.asp.* Any questions regarding this process should be referred to the SSVF Program Office via email at *SSVF@va.gov.* For detailed SSVF program information and requirements, see 38 CFR part 62.

B. Content and Form of Application: Applicants are strongly encouraged to submit applications electronically following instructions found at *www.va.gov/homeless/ssvf.asp.* Alternatively, applicants can mail in applications. If mailed, applicants must submit two completed collated, hard copies of the application and two CDs containing electronic versions of the entire application. Each application copy must: (i) Be fastened with a binder clip, and (ii) contain tabs listing the major sections of and exhibits to the application. Each CD must be labeled with the applicant's name and must contain an electronic copy of the entire application. A budget template must be attached in Excel format on the CD, but all other application materials may be attached in a PDF or other format.

C. Submission Dates and Times: Applications for supportive services grants under the SSVF Program must be received by the SSVF Program Office by 4:00 p.m., Eastern Standard Time on February 3, 2017. Awards made for supportive services grants will fund operations beginning October 1, 2017. Applications must arrive as a complete package. Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected. Additionally, in the interest of fairness to all competing applicants, this deadline is firm as to date and hour, and VA will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays, computer service outages, or other delivery-related problems.

D. Intergovernmental Review: This section is not applicable to the SSVF program.

E. Funding Restrictions: Funding will be awarded for supportive services grants under this NOFA depending on funding availability (currently funding is only authorized to be appropriated for the SSVF program through FY 2017). Applicants should fill out separate applications for each supportive services funding request. Funding will be awarded under this NOFA to new and existing grantees for a 1 to 3-year period beginning October 1, 2017.

F. Other Submission Requirements:

1. Existing applicants applying for Priority 1 or 2 grants may apply only as renewal applicants using the application designed for renewal grants.

2. Existing or new applicants applying for new funding under Priority 3 must use the application designed for new grants.

3. At the discretion of VA, multiple grant proposals submitted by the same lead agency may be combined into a single grant award if the proposals provide services to contiguous areas. Any funds awarded pursuant to section V.5. will be combined into a single award.

4. Additional supportive services grant application requirements are specified in the application package. Submission of an incorrect or incomplete application package will result in the application being rejected during threshold review. The application packages must contain all required forms and certifications. Selections will be made based on criteria described in 38 CFR part 62 and this NOFA. Applicants and grantees will be notified of any additional information needed to confirm or clarify information provided in the application and the deadline by which to submit such information. Applicants are strongly encouraged to submit applications electronically. If mailed, applications and CDs must be submitted to the following address: SSVF Program Office, National Center on Homelessness Among Veterans, 4100 Chester Avenue, Suite 201,

Philadelphia, PA 19104. Applicants must submit two hard copies and two CDs. Applications may not be sent by facsimile (FAX).

V. Application Review Information

A. Criteria:

1. VA will only score applicants that meet the threshold requirements described in 38 CFR 62.21.

2. VA will use the criteria described in 38 CFR 62.22 to score a new application (Priority 3) for a supportive services grant and criteria in 38 CFR 62.24 to score grantees applying for renewal (Priority 1 and 2) of a supportive services grant.

B. Review and Selection Process: VA will review all supportive services renewal grant applications in response to this NOFA according to the following steps:

1. Score all applications that meet the threshold requirements described in 38 CFR 62.21.

2. Rank those applications who score at least 75 cumulative points and receive at least one point under each of the categories identified for new applicants in 38 CFR 62.22 and renewal applicants in 38 CFR 62.24. The applications will be ranked in order from highest to lowest scores in accordance with 38 CFR 62.23 for new applicants and 38 CFR 62.25 for renewal applicants.

3. Utilize the ranked scores of applications as the primary basis for selection. However, VA will also utilize the following considerations in 38 CFR 62.23(d) to select applicants for funding:

(a) Give preference to applications that provide or coordinate the provision of supportive services for very low-income Veteran families transitioning from homelessness to permanent housing. Consistent with this preference, where other funds from community resources are not readily available for temporary financial assistance, applicants are required to spend no less than 60 percent of all budgeted temporary financial assistance on participants occupying permanent housing as defined in 38 CFR 62.11(b). Waivers to this 60 percent requirement may be requested when grantees can demonstrate significant local progress towards eliminating homelessness in the target service area. Waiver requests must include data from authoritative sources such as USICH certification that a community has ended homelessness as defined by Federal Benchmarks and Criteria or have reached Community Solution's Functional Zero (*https://cmtysolutions.org/sites/default/files/final_zero_2016_metrics.pdf*). Waivers for the 60 percent requirement may also be requested for services provided to rural Indian tribal areas and other rural areas where shelter capacity is insufficient to meet local need. Waiver requests must include an endorsement by the impacted CoC explicitly stating that a shift in resources from rapid re-housing to prevention will not result in an increase in homelessness.

(b) To the extent practicable, ensure that supportive services grants are equitably distributed across geographic regions, including rural communities and tribal lands. This equitable distribution criteria will be used to ensure that SSVF resources are provided to those communities with the highest need as identified by VA's assessment of expected demand and available resources to meet that demand.

4. Subject to the considerations noted in paragraph B.3 above, VA will fund the highest-ranked applicants for which funding is available.

5. VA may in its discretion offer to award a non-renewed grant to the highest-ranked applicant that is awarded a grant in the same community as, or a proximate community to, the non-renewed grant, so long as that applicant has the capacity to promptly begin providing services in connection with all awards. If that applicant declines the award, VA will offer the award to the next highest-ranked applicant and continue in that manner until a qualifying grantee accepts the award.

VI. Award Administration Information

A. Award Notices: Although subject to change, the SSVF Program Office expects to announce grant recipients for all applicants in the fourth quarter of FY 2017 with grants beginning October 1, 2017. Prior to executing a funding agreement, VA will contact the applicants and make known the amount of proposed funding and verify that the applicant would still like the funding. Once VA verifies that the applicant is still seeking funding, VA will execute an agreement and make payments to the grant recipient in accordance with 38 CFR part 62 and this NOFA.

B. Administrative and National Policy Requirements: It is VA policy to support a ''Housing First'' model in addressing and ending homelessness. Housing First establishes housing stability as the primary intervention in working with homeless persons. The Housing First approach is based on research that shows that a homeless individual or household's first and primary need is to obtain stable housing, and that other issues that may affect the household can and should be addressed as housing is obtained. Housing is not contingent on compliance with services; instead, participants must comply with a standard lease agreement and are provided with the services and supports that are necessary to help them do so successfully. Research supports this approach as an effective means to end homelessness.

Consistent with the Housing First model supported by VA, grantees are expected to offer the following supportive services: housing counseling; assisting participants in understanding leases; securing utilities; making moving arrangements; providing representative payee services concerning rent and utilities when needed; and mediation and outreach to property owners related to locating or retaining housing. Grantees may also assist participants by providing rental assistance, security or utility deposits, moving costs or general housing stability assistance, using other Federal resources, such as the ESG, or supportive services grant funds to the extent described in this NOFA and 38 CFR 62.34.

As SSVF grants cannot be used to fund treatment for mental health or substance use disorders, applicants must provide evidence that they can provide access to such services to all program participants through formal and informal agreements with community providers.

C. Reporting: VA places great emphasis on the responsibility and accountability of grantees. As described in 38 CFR 62.63 and 62.71, VA has procedures in place to monitor supportive services provided to participants and outcomes associated with the supportive services provided under the SSVF program. Applicants should be aware of the following:

1. Upon execution of a supportive services grant agreement with VA, grantees will have a VA regional coordinator assigned by the SSVF Program Office who will provide oversight and monitor supportive services provided to participants.

2. Grantees will be required to enter data into a Homeless Management Information System (HMIS) Web-based software application. This data will consist of information on the participants served and types of supportive services provided by grantees. Grantees must treat the data for activities funded by the SSVF program separate from that of activities funded by other programs. Grantees will be required to work with their HMIS Administrators to export client-level data for activities funded by the SSVF Program to VA on at least a monthly basis.

3. VA shall complete annual monitoring evaluations of each grantee. Monitoring will also include the submittal of quarterly and annual financial and performance reports by the grantee. The grantee will be expected to demonstrate adherence to the grantee's proposed program concept, as described in the grantee's application. All grantees are subject to audits conducted by the VA or its representative. Grantees will be required to provide each participant with a satisfaction survey which can be submitted by the participant directly to VA within 30 days of such participant's pending exit from the grantee's program.

5. Grantees will be assessed based on their ability to meet critical performance measures. In addition to meeting program requirements defined by the regulations and applicable NOFA(s), grantees will be assessed on their ability to place participants into housing and the housing retention rates of participants served. Higher placement for homeless participants and higher housing retention rates for at-risk participants are expected for very-low income Veteran families when compared to extremely low-income Veteran families with incomes below 30 percent of the area median income.

6. Organizations receiving renewal awards and that have had ongoing SSVF program operation for at least 1 year (as measured from the start of initial SSVF services until December 5, 2016) may be eligible for a 3-year award. Grantees meeting outcome goals defined by VA and in substantial compliance with their grant agreements (defined by meeting targets and having no outstanding corrective action plans) and who, in addition, receive 3-year accreditation from the Commission on Accreditation of Rehabilitation Facilities (CARF) in Employment and Community Services: Rapid Rehousing and Homeless Prevention standards or a 4-year accreditation from the Council on Accreditation's (COA) accreditation in Supported Community Living Services standards or a 3 year accreditation in The Joint Commission's Behavioral Health Care: Housing Support Services Standards are eligible for a 3-year grant renewal subject to funding availability (NOTE: Multi-year awards are contingent on funding availability). If awarded a multiple year renewal, grantees may be eligible for funding increases as defined in NOFAs that correspond to years 2 and 3 of their renewal funding.

VII. Agency Contact

For Further Information Contact: John Kuhn, National Director, SSVF at the following email address: *SSVF@va.gov.*

VIII. Other Information

A. VA Goals and Objectives for Funds Awarded Under this NOFA: In accordance with 38 CFR 62.24(c), VA will evaluate an applicant's compliance with VA goals and requirements for the SSVF Program. VA goals and requirements include the provision of supportive services designed to enhance the housing stability and independent living skills of very low-income Veteran families occupying permanent housing across geographic regions and program administration in accordance with all applicable laws, regulations, and guidelines. For purposes of this NOFA, VA goals and requirements also include the provision of supportive services designed to rapidly re-house or prevent homelessness among people in the following target populations who also meet all requirements for being part of a very low-income Veteran family occupying permanent housing:

1. Veteran families earning less than 30 percent of area median income as most recently published by HUD for programs under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f) (*http://www.huduser.org*).

2. Veterans with at least one dependent family member.

3. Veterans returning from Operation Enduring Freedom, Operation Iraqi Freedom, or Operation New Dawn.

4. Veteran families located in a community, as defined by HUD's CoC, or a county not currently served by a SSVF grantee.

5. Veteran families located in a community, as defined by HUD's CoC, where current level of SSVF services is not sufficient to meet demand of Category 2 and 3 (currently homeless) Veteran families.

6. Veteran families located in a rural area.

7. Veteran families located on Indian Tribal Property.

B. Payments of Supportive Services Grant Funds: Grantees will receive payments electronically through the U.S. Department of Health and Human Services Payment Management System. Grantees will have the ability to request payments as frequently as they choose subject to the following limitations:

1. During the first quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 35 percent of the total supportive services grant award without written approval by VA.

2. By the end of the second quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 60 percent of the total supportive services grant award without written approval by VA.

3. By the end of the third quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 80 percent of the total supportive services grant award without written approval by VA.

4. By the end of the fourth quarter of the grantee's supportive services annualized grant award period, the grantee's cumulative requests for supportive services grant funds may not exceed 100 percent of the total supportive services grant award.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on December 1, 2016, for publication.

Michael Shores,

Acting Director, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2016–29269 Filed 12–2–16; 11:15 am]

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DEPARTMENT OF VETERANS AFFAIRS

Allowance for Private Purchase of an Outer Burial Receptacle in Lieu of a Government-Furnished Graveliner for a Grave in a VA National Cemetery

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is updating the monetary allowance payable for qualifying interments that occur during calendar year 2017, which applies toward the private purchase of an outer burial receptacle (or ''graveliner'') for use in a VA national cemetery. The allowance is equal to the average cost of Government-furnished graveliners less any administrative costs to VA. The purpose of this Notice is to notify interested

parties of the average cost of Government-furnished graveliners, administrative costs that relate to processing and paying the allowance and the amount of the allowance payable for qualifying interments that occur during calendar year 2017.

FOR FURTHER INFORMATION CONTACT: William Carter, Budget Operations and Field Support Division, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. Telephone: (202) 461–9764 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 2306(e)(3) and (4) of title 38, United States Code (U.S.C.) authorizes VA to provide a monetary allowance for the private purchase of an outer burial receptacle for use in a VA national cemetery where its use is authorized. The allowance for qualified interments that occur during calendar year 2017 is the average cost of Government-furnished graveliners in fiscal year 2016, less the administrative costs incurred by VA in processing and paying the allowance in lieu of the Government-furnished graveliner.

The average cost of Government-furnished graveliners is determined by taking VA's total cost during a fiscal year for single-depth graveliners that were procured for placement at the time of interment and dividing it by the total number of such graveliners procured by VA during that fiscal year. The calculation excludes both graveliners procured and pre-placed in gravesites as part of cemetery gravesite development projects and all double-depth graveliners. Using this method of computation, the average cost was determined to be $351.00 for fiscal year 2016.

The administrative costs incurred by VA consist of those costs that relate to processing and paying an allowance in lieu of the Government-furnished graveliner. These costs have been determined to be $9.00 for calendar year 2017.

The allowance payable for qualifying interments occurring during calendar year 2017, therefore, is $342.00.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on December 1, 2016, for publication.

Dated: December 1, 2016.

Michael Shores,

Acting Director, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2016–29273 Filed 12–6–16; 8:45 am]

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Part II

Department of Health and Human Services

Office of Inspector General

42 CFR Parts 1003 and 1005

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1003 and 1005

RIN 0936–AA04

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the civil monetary penalty (CMP or penalty) rules of the Office of Inspector General to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments, and exclusions to improve readability and clarity.

DATES: These regulations are effective on January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Katie Arnholt or Geoff Hymans at (202) 619–0335, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Regulatory Action

The Affordable Care Act of 2010 (Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, 124 Stat. 1029 (2010), hereafter the ACA) significantly expanded OIG's authority to protect Federal health care programs from fraud and abuse. The OIG proposed to update its regulations to codify the changes made by the ACA in the regulations. At the same time, OIG proposed updates pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other statutory authorities, as well as technical changes to clarify and update the regulations.

B. Legal Authority

The legal authority, laid out later in the preamble, for this regulatory action is found in the Social Security Act (the Act), as amended by the ACA. The legal authority for the changes is listed by the parts of Title 42 of the Code of Federal Regulations that we proposed to modify:

1003: 42 U.S.C. 1320a–7(c), 1320a–7a, 1320b–10, 1395w–27(g), 1395w–112(b)(3)(E), 1395w–141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 1396r–8(b)(3)(B), 1396r–8(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a.

1005: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a, and 1320c–5.

C. Summary of Major Provisions

We proposed changes to the Civil Monetary Penalties (CMP) regulations at 42 CFR part 1003 to implement or codify authorities under the ACA and other statutes. The ACA provides for CMPs, assessments, and exclusion for:

- Failure to grant OIG timely access to records;
- ordering or prescribing while excluded;
- making false statements, omissions, or misrepresentations in an enrollment application;
- failure to report and return an overpayment; and
- making or using a false record or statement that is material to a false or fraudulent claim.

These statutory changes are reflected in the proposed regulations.

We also proposed a reorganization of 42 CFR part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme. We proposed an alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill Federal health care programs for furnishing items or services. We also clarified the liability guidelines under OIG authorities, including the Civil Monetary Penalties Law (CMPL); the Emergency Medical Treatment and Labor Act (EMTALA); section 1140 of the Act for conduct involving electronic mail, Internet, and telemarketing solicitations; and section 1927 of the Act for late or incomplete reporting of drug-pricing information.

D. Costs and Benefits

There are no significant costs associated with the regulatory revisions that would impose any mandates on State, local, or tribal governments or the private sector. The OIG anticipates that CMP collections may increase in the future in light of the new CMP authorities and other changes proposed in this rule. However, it is difficult to accurately predict the extent of any increase because of a variety of factors, such as budget and staff resources, the number and quality of CMP referrals or other potential cases, and the time needed to investigate and litigate a case. In calendar years 2004–2015, OIG collected annual amounts ranging between $10.2 million and $107.3 million in CMP resolutions for a total of over $309.2 million.

I. Discussion

A. Summary of Revisions and Response to Comments

In response to the notice of proposed rulemaking, 79 FR 27,080 (May 12, 2014), OIG received 27 public comments from various health care providers and organizations, professional medical societies and associations, and other interested parties. We also received a comment that was filed one day late, which we included in our responses. The comments included both concerns regarding the general factors and more detailed comments on specific CMP provisions.

Set forth below is a discussion of the proposed changes to the regulations at the 42 CFR part 1003, a synopsis of the various comments and recommendations received in response to the proposed rule, our response to those comments and recommendations, and a summary of the specific revisions and clarifications being made to the regulations as a result of the public comments.

B. Background

For over 27 years, OIG has exercised the authority to impose CMPs, assessments, and exclusions in furtherance of its mission to protect Federal health care programs and their beneficiaries from fraud, waste, and abuse. As those programs have changed over the last two decades, OIG has received new fraud-fighting CMP authorities, including new authorities under the ACA. With the addition of new authorities over time, part 1003 has become cumbersome. While adding new authorities, we are also reorganizing part 1003 to improve its readability and clarity and addressing several substantive issues in our existing authorities.

In 1981, Congress enacted the CMPL, section 1128A of the Act (42 U.S.C. 1320a–7a), as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The CMPL authorized the Secretary to impose penalties and assessments on a person, as defined in 42 CFR part 1003, who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMPL also authorized the Secretary to exclude persons from Medicare and all State health care programs (including Medicaid). Congress later expanded the CMPL and the scope of exclusion to apply to all Federal health care programs. The Secretary delegated the CMPL's authorities to OIG. 53 FR 12,993 (April 20, 1988). Since 1981, Congress has

created various other CMP authorities covering numerous types of fraud and abuse. These new authorities were also delegated by the Secretary to OIG and were added to part 1003.

The ACA is the most recent expansion of the CMP provisions and OIG's ability to protect Federal health care programs from fraud and abuse. Sections 6402(d)(2)(A)(iii) and 6408(a) of ACA amended the CMPL by adding new conduct that subjects a person to penalties, assessments, and/or exclusion from participation in Federal health care programs. The new covered conduct includes: (1) Failure to grant OIG timely access to records, upon reasonable request; (2) ordering or prescribing while excluded when the excluded person knows or should know that the item or service may be paid for by a Federal health care program; (3) making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a Federal health care program; (4) failure to report and return an overpayment; and (5) making or using a false record or statement that is material to a false or fraudulent claim. *See* the Act, section 1128A(a)(8)–(12). We are codifying these new authorities and remedies at 42 CFR 1003.200(b)(6)–(10), 1003.210(a)(6)–(9), and 1003.210(b)(3).

Section 6408(b)(2) of the ACA amended section 1857(g)(1) of the Act (42 U.S.C. 1395w–27(g)(1)), which relates to Medicare Advantage and Part D contracting organizations. *See* the Act, section 1860D–12(b)(3)(E) (42 U.S.C. 1395w–112) (incorporating 1857(g) by reference). Through this amendment to the Act, the ACA made several changes to these authorities. First, section 6408(b)(2) of the ACA clarifies that penalties, and, where applicable, assessments, may be imposed against a Medicare Advantage or Part D contracting organization when its employees or agents, or any provider or supplier who contracts with it, engages in the conduct described in the CMP authorities in section 1857(g) of the Act. This statutory change broadens the general liability of principals for the actions of their agents under our existing regulations at § 1003.102(d)(5) (proposed § 1003.120(c)) to include contracting providers and suppliers who may not qualify as agents of the contracting organization. The ACA also provides for penalties and assessments against a Medicare Advantage or Part D contracting organization that: (1) Enrolls an individual without his or her prior consent; (2) transfers an enrollee from one plan to another without his or her prior consent; (3) transfers an enrollee solely for the purpose of earning a commission; (4) fails to comply with marketing restrictions described in sections 1851(h) or (j) of the Act (42 U.S.C. 1395w–21(h) or (j)) or applicable implementing regulations or guidance; or (5) employs or contracts with any person who engages in the conduct described in section 1857(g)(1) of the Act.

We have codified these new authorities in the proposed regulations at § 1003.400(c) and their corresponding penalties and assessments at § 1003.410. The Centers for Medicare & Medicaid Services (CMS) may also impose sanctions under its authorities related to Medicare Advantage or Part D contracting organizations. Those authorities are at 42 CFR parts 422 and 423.

C. Reorganization of Part 1003

We proposed reorganizing part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme. Except for general and procedural subparts, the reorganized part 1003 groups CMP authorities into subparts by subject matter. This revised structure also clarifies the differences between the various CMP authorities and their respective statutory remedies. For certain CMP authorities, penalties, assessments, and exclusion are authorized. For other CMP authorities, only penalties, or penalties and assessments, are authorized. Each subpart is intended to be self-contained, with all the relevant provisions concerning a particular violation included in the same subpart.

We received no comments on the reorganization and finalize it as proposed.

D. Technical Changes and Clarifications

Because we intended each subpart to be self-contained, we proposed incorporating the exclusion sections, which were found at §§ 1003.105 and 1003.107, into the subparts in which exclusion is available: False Claims; Anti-kickback and Physician Self-Referral; EMTALA; and Beneficiary Inducement. This proposed revision more clearly reflects the statutory scheme, which permits both monetary and exclusion remedies for these violations.

The proposed changes clarify in each subject matter subpart that we may impose a penalty for each individual violation of the applicable provision. As we explained in the notice of proposed rulemaking, and below, the statutory authorities are clear that each act that constitutes a violation is subject to penalties. The proposed revisions to the regulatory language better reflect this statutory framework.

Throughout part 1003, we proposed replacing references to Medicare and State health care programs with ''Federal health care programs'' when the provision concerns exclusion to more completely reflect the full scope of exclusion. The proposed changes also remove all references to the penalties and assessments available before 1997 because any conduct prior to 1997 falls outside the CMPL's statute of limitations.

The proposed changes clarify that a principal's liability for the acts of its agents does not limit liability only to the principal. Agents are still liable for their misconduct. In our enforcement litigation, we have encountered the argument that agents are not liable for their misconduct where the principal is liable for the same misconduct. We believed the law provides that the agent remains liable for his or her conduct and may not use the principal as a liability shield. The proposed revision clarifies this point. In addition, we proposed to consolidate § 1003.102(d)(1)–(4), which addressed situations in which multiple parties may have liability for separate CMP provisions. This proposed revision clarifies that each party may be held liable for any applicable penalties and that the parties may be held jointly and severally liable for the assessment.

We received no comments on these topics and finalize the regulation as proposed.

Under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114–74, 129 Stat. 599), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890), Federal agencies must make annual adjustments to their CMPs, including the CMPs in the Social Security Act. The Department of Health and Human Services (HHS or the Department) will publish all of the Department's adjusted CMP amounts at 45 CFR part 102. That section will include CMPs that have been delegated to OIG. To ensure transparency, we have added footnotes to subparts B through M stating that the penalty amounts are adjusted for inflation and citing to 45 CFR part 102.

E. Civil Monetary Penalty Authorities

Subpart A—General Provisions

Subpart A contains the general provisions that apply to part 1003. The proposed changes revised the ''Basis and Purpose'' section to state more succinctly part 1003's purpose and to

include a complete listing of CMPs. We also proposed updates to statutory authority citations at proposed § 1003.100(a)–(b).

We received no comments on these changes and finalize the regulations as proposed.

1003.110 Definitions

The proposed rule included several changes to the ''Definitions'' section for clarity and readability. First, we proposed to redesignate § 1003.101 as § 1003.110. We proposed to remove terms from this part that duplicate definitions in part 1000 or are no longer used in this part. We also proposed the following changes and additions to the specific definitions.

Claim

We proposed to revise the definition of ''claim'' by changing the word ''to'' to ''under.'' This change more closely aligns the regulations to the CMPL's definition of ''claim'' to avoid any misinterpretation that a claim is limited to an application for payment for an item or service made directly to a Federal health care program (*e.g.,* a claim also includes applications for payment to contractors).

Contracting Organization

We proposed to update the definition of ''contracting organization'' to include all entities covered by sections 1857, 1860D–12, 1876(b) (42 U.S.C. 1395mm(b)), or 1903(m) of the Act.

Item or Service

We proposed revisions to the definition of the term ''item or service.'' Section 1128A of the Act provides that the term ''item or service'' ''includes'' various items, devices, supplies, and services. By using the word ''includes'' in section 1128A of the Act, Congress created an illustrative statutory definition that is broad enough to capture all the uses of the term in section 1128A of the Act. The term is used in section 1128A of the Act in two different contexts: one, in reference to submitting claims for items and services reimbursed by a Federal health care program, and two, in the definition of ''remuneration'' to beneficiaries in reference to section 1128A(a)(5) of the Act. We proposed clarifying the definition to ensure that it reflects the broad meaning of ''item or service'' in both contexts.

Knowingly

We proposed clarifying the definition of ''knowingly,'' found in the existing regulation at § 1003.102(e), to cover acts as opposed to information. We also proposed removing the reference to the False Claims Act (FCA) from the definition of ''knowingly'' because it is unnecessary. As used in part 1003, the term ''knowingly'' applies only to acts, such as the act of presenting a claim. When a person's awareness or knowledge of information is at issue, the CMPL and other statutes use either a ''knows or should know'' or a ''knew or should have known'' construction. For example, section 1128A(a)(2) of the Act subjects a person to liability when the person knowingly presents, or causes to be presented, a claim that the person knew or should have known is false or fraudulent. Here, the act is presenting the claim or causing the claim to be presented. The information is that the claim was false or fraudulent.

Material

We proposed a definition of ''material'' that mirrors the FCA definition as ''having a tendency to influence, or be capable of influencing, the payment or receipt of money or property.''

Overpayment

We proposed a definition of ''overpayment'' that is taken from section 1128J(d)(4) of the Act (42 U.S.C. 1320a-7k(d)(4)), as amended by section 6402(a) of the ACA.

Reasonable Request

We proposed a definition of ''reasonable request'' as part of implementing the new ACA CMP authority for failure to grant OIG timely access to records, as discussed below under § 1003.200, subpart B.

Responsible Official

We proposed a definition of ''Responsible Official'' as this term relates to the select agent and toxin CMP authority. We proposed to amend the definition of ''select agent and toxin'' as the term relates to the select agent and toxin CMP authority (42 U.S.C. 262a(i); Act, section 1128A(j)(2)).

Responsible Physician

We also proposed revising the definition of ''responsible physician'' to more closely conform to statutory intent, as discussed below under § 1003.500, subpart E.

Separately Billable Item or Service and Non-Separately-Billable Item or Service

We also proposed definitions of ''separately billable item or service'' and ''non-separately-billable item or service'' to create an alternate method for calculating penalties and assessments for violations of section 1128A(a)(6) of the Act.

We did not receive comments on the proposed definitions of ''claim,'' ''contracting organization,'' ''item or service,'' ''Responsible Official,'' ''non-separately-billable item or service,'' or ''separately billable item or service'' and are finalizing the definition as proposed. We received comments on the definition of ''knowingly,'' ''should know, or should have known,'' ''material,'' and ''timely basis,'' which are discussed below. We also received comments on the definitions of ''overpayment,'' ''reasonable request,'' and ''responsible physician,'' which we will address in the discussion of the overpayment, timely access, and EMTALA CMPs respectively.

Comment: One commenter recommended that the definitions of ''knowingly'' and ''should know, or should have known'' not include that ''no proof of specific intent to defraud is required.'' Another commenter recommended that, when applied to § 1003.200(b)(7) for false statements, omissions, or misrepresentations, ''knowingly'' should include a specific intent to defraud. Both commenters argued that, where there was no specific intent to defraud, a maximum penalty of $50,000 for a violation of § 1003.200(b)(7) would be unduly harsh.

Response: The definition of ''should know'' in section 1128A(i)(7) of the Act states that ''no proof of specific intent to defraud is required.'' Similarly, the existing regulatory definitions of ''knowingly'' and ''should know, or should have known'' both state that ''no proof of specific intent is required.'' We proposed no changes to that language in either definition. As discussed above, our proposal clarified that the use of the term ''knowingly'' referred to acts, such as submitting a claim, and ''should know or should have known'' referred to information, such as the claim was false or fraudulent. Further, OIG does not believe it would be unduly harsh to apply up to a $50,000 penalty where a person acted with reckless disregard when making a material omission on an application, bid, or contract to participate or enroll as a provider or supplier. We are finalizing these terms, as proposed.

Comment: Some commenters disagreed with the proposed definition of ''material'' and recommended we adopt a definition of ''having an actual influence on the payment or receipt of money or property.''

Response: We respectfully disagree with the commenters and finalize the definition, as proposed. The proposed language mirrors the definition of

material in the FCA, 31 U.S.C. 3729(b)(4). In the ACA, Congress added a new CMP cause of action against persons who knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program. This cause of action mirrors a cause of action under the FCA at 31 U.S.C. 3729(a)(1)(B). We believe that the same definition should apply in the CMPL given the similarities with the FCA. In addition, we believe this definition is appropriate for the other CMP causes of action in this part that use the term ''material'' because those authorities also involve the use of false statements—§§ 1003.200(a)(4)(ii), 1003.200(a)(7), 1003.200(d), and 1003.1100(a).

Comment: One commenter argued that we should change the definition of ''timely basis'' to the 60-day period from the time the individual or entity knows that the amounts collected violated the Physician Self-Referral Law. The commenter states that it is unreasonable to expect individuals and entities consistently to know, within 60 days of collection, that an amount was collected in violation of the Stark Law, and that it would be unfair to impose penalties, assessments, and exclusions on individuals and entities for failure to return payments that they did not know were collected in violation of the Stark Law.

Response: Because we did not propose changing the language of the definition, only the internal citation, this suggestion is outside the scope of this rulemaking. We are finalizing the definition, as proposed.

Comment: We also received a comment asking that OIG clarify that the provisions of part 1003 applying to Federal health care programs do not apply to Qualified Health Plan Issuers or State-based or Federally facilitated exchanges.

Response: ''Federal health care program'' is defined in section 1128B(f) of the Act. part 1003 does not include a definition of ''Federal health care program'' and none was included in our proposed changes to that part. Therefore, this comment is beyond the scope of the rulemaking. That said, the Department stated in an October 30, 2013 letter from the Secretary to Representative Jim McDermott that it does not consider Qualified Health Plans (QHPs) or other programs related to the Federally facilitated marketplace to be federal health care programs, for the purposes of 1128B(f) of the Act.

1003.140 Determinations Regarding the Amount of Penalties and Assessments and the Period of Exclusion

We proposed modifying the provisions relating to the factors considered in determining exclusion periods and the amount of penalties and assessments for violations. The existing structure separately listed factors for certain CMP violations in § 1003.106(a) and provided additional detail on these factors for certain CMP violations in § 1003.106(b) and (d). This structure was cumbersome and potentially confusing for the reader.

To add clarity and improve transparency in OIG's decision-making, we identified the most common issues among the factors listed and created a single, primary list of factors in the proposed § 1003.140. The primary factors are: (1) The nature and circumstances of the violation, (2) the degree of culpability of the person, (3) the history of prior offenses, (4) other wrongful conduct, and (5) other matters as justice may require. As the fifth factor demonstrates, these are illustrative factors rather than a comprehensive list. These factors would apply to all CMP violations, except as otherwise provided in the subpart relating to a specific subject matter, which may contain additional detail or explanation regarding a factor's applicability to a specific violation. For example, the aggravating factors listed in § 1003.106(b)(1) related to the nature and circumstances of a violation. Because these factors relate most directly to billing issues, the proposed regulations include them in §§ 1003.220, 1003.320, and 1003.420. We proposed updating the claims-mitigating factor by increasing the maximum dollar amount considered as mitigation from $1,000 to $5,000. We believed this updated amount is an appropriate threshold that is consistent with rationale behind the original amount. A dollar threshold as a mitigating factor for CMP purposes differentiates between conduct that could be considered less serious and more serious. Conduct resulting in more than $5,000 in Federal health care program loss is an indication of more serious conduct. Given the changes in the costs of health care since this regulation was last updated in 2002, we believed the $1,000 threshold was lower than appropriate. We also proposed revising the claims-aggravating factor that was at 1003.106(b)(1)(iii) by replacing ''substantial'' with ''$15,000 or more.'' We believe that replacing ''substantial'' with a specific dollar threshold increases transparency and gives providers better guidance on OIG's evaluation of this factor. In assigning a dollar value to the aggravating factor, we considered our practices in evaluating conduct for pursuing CMPs and proposed that a loss greater than $15,000 is an indication of serious misconduct. As discussed in response to comments, we are finalizing the aggravating factor as a loss greater than $50,000.

The OIG will, however, continue to review the facts and circumstances of a violation on a case-by-case basis. For instance, when considering the nature and circumstances of any case, OIG will consider, among other things and to the extent they are relevant, the period over which the conduct occurred, whether a pattern of misconduct is indicated, the magnitude of the violation, the materiality or significance of a false statement or omission, the number of people involved, the number of victims, and whether patients were or could have been harmed.

The proposed changes also clarify that these factors apply to exclusion determinations made under part 1003 as well as penalty and assessment amount determinations. We are removing § 1003.107(c) in light of this reorganization. The existing regulations stated, at § 1003.107(c), that the guidelines regarding exclusion determinations are not binding. This language was used to emphasize that only the reasonableness of a period of exclusion is reviewable on appeal as opposed to OIG's decision to impose an exclusion. While OIG's discretion to exercise its exclusion authority remains unreviewable, the § 1003.107(c) language is no longer necessary under the proposed reorganization. The revisions at § 1003.140 more clearly state that the general guidelines relate to the length of exclusion as opposed to the decision whether to exclude a person.

At § 1003.106(b)(2), the regulations discussed a person's degree of culpability and listed several aggravating circumstances concerning whether a person had knowledge of the violation. We believed the language was out-of-date in light of all the CMP authorities that have been added to part 1003 over the years. We proposed to consider as an aggravating factor a person's having a level of intent to commit the violation that is greater than the minimum intent required to establish liability.

Various CMP authorities have different intent or scienter requirements. Some authorities have a ''knows or should know'' standard consistent with

the FCA standard that includes actual knowledge, deliberate ignorance, or reckless disregard. Some authorities require only negligence and some have no intent requirement. In CMP cases in which the scienter standard required to prove a violation is lower than actual knowledge, having actual knowledge is more egregious. Our existing regulations provide that actual knowledge is an aggravating factor when a respondent knew an item or service was not provided as claimed or if the respondent knew that a claim was false or fraudulent. We intend the general ''degree of culpability'' factor to encompass this approach and to extend to all CMP authorities that have a scienter standard that is lower than actual knowledge. In response to comments, as summarized below, we are finalizing the rule to provide that it shall be considered an aggravating factor when a person has actual knowledge and the level of intent required to establish liability is less than actual knowledge.

Possessing the lowest level intent to commit a violation is not a defense against liability, a mitigating factor, or a justification for a less serious remedy. Individuals and entities are expected to know the law and Federal health care program rules. While the degree of culpability is relevant in our determination to impose a monetary or exclusion remedy, other factors, such as the nature and circumstances of the violation, may justify a maximum monetary remedy or exclusion to protect Federal health care programs and beneficiaries from fraud, waste, and abuse.

In addition, we proposed to add a mitigating circumstance to the degree-of-culpability factor for taking ''appropriate and timely corrective action in response to the violation.'' The proposed regulation required that a person, to qualify as taking corrective action, disclose the violation to OIG through the Self-Disclosure Protocol (the Protocol) and fully cooperate with OIG's review and resolution of the violation. We have long emphasized the importance of compliance programs that result in appropriate action when Federal health care program compliance issues are identified. We continue to believe that appropriate action for potential violations of OIG's CMP authorities must include self-disclosure and cooperation in the inquiry and resolution of the matter. For most OIG CMP authorities, the person should not qualify for mitigation of the potential monetary or exclusion remedies without self-disclosure through the Protocol (available at—*http://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp*). In response to comments, which are summarized below, we are finalizing the rule to include self-disclosure to CMS's Self-Referral Disclosure Protocol for Stark violations. As further discussed in subpart E, we are also including disclosure to CMS for EMTALA violations.

The proposed changes clarified that when we are determining the appropriate remedy against an entity, aggravating circumstances include the prior offenses or other wrongful conduct of: (1) The entity itself; (2) any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act (42 U.S.C. 1320a–3)) in the entity at the time the violation occurred and who knew, or should have known, of the violation; or (3) any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act (42 U.S.C. 1320a–5)) of the entity at the time the violation occurred. For ''prior offenses,'' we also proposed to change ''any other public or private program for reimbursement for medical services'' to ''in connection with the delivery of a health care item or service.'' This proposed change is consistent with the aggravating circumstance ''other wrongful conduct.''

Finally, the proposed rule clarified when OIG considers the financial condition of a person in determining penalty or assessment amounts. The regulations discussed financial condition in various sections with varying degrees of specificity: § 1003.106(a)(1)(iv); (a)(3)(i)(F); (a)(4)(iv); (b)(5); and (d)(4). We proposed a more uniform and specific standard to apply after OIG evaluates the facts and circumstances of the conduct and weighs the aggravating and mitigating factors to determine an appropriate penalty and assessment amount. Once OIG proposes this penalty and assessment amount, the person may request that OIG consider its ability to pay the proposed amount. To permit OIG to evaluate a person's ability to pay, the person must submit sufficient documentation that OIG deems necessary to conduct its review, including, but not limited to, audited financial statements, tax returns, and financial disclosure statements. This ability-to-pay review may also consider the ability of the person to reduce expenses or obtain financing to pay the proposed penalty and assessment. If a person requested a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review would be that which the person submitted to OIG, unless the Administrative Law Judge (ALJ) finds that extraordinary circumstances prevented the person from providing the financial documentation to OIG in the time and manner requested by OIG prior to the hearing request.

We received the following comments on these proposals. To the extent the comments do not address aspects of these changes, we are finalizing this section of the rule, as proposed.

Comment: Some commenters disagreed with our proposal to include a person's level of intent as an aggravating factor for several reasons. Some commenters viewed proving, and distinguishing between, different degrees of mental states, such as ''actual knowledge,'' ''deliberate ignorance,'' and ''reckless disregard,'' as subjective. Commenters argued that the proposed rule's rationale for using degrees of scienter to determine the existence of aggravating circumstances is not sufficient to overcome concerns regarding the subjectivity involved in distinguishing between and proving these highly nuanced mental states. Aside from the statement that ''actual knowledge is considered more egregious than a lower level of intent,'' commenters expressed concern that the proposed rule does not explain which different scienter requirements carry respectively greater, or lesser, culpability. For example, commenters argued that the proposed rule does not provide if or how scienter requirements, such as ''reckless disregard'' and ''deliberate ignorance,'' relate to one another with respect to potential culpability. Commenters were also concerned that the proposed rule does not set forth the evidentiary standards required to prove, and distinguish between, degrees of scienter, (*e.g.,* where a person can be held liable: (1) For *knowingly* presenting an inaccurate claim; or (2) where the person *knew, or should have known,* that the claim was not accurate). Given that legal expertise is typically required to fully interpret and understand these terms, commenters stated that physicians and health care providers may not fully comprehend the changes proposed by the rule and may be disadvantaged when trying to respond to OIG's determination that an aggravating circumstance is present on the basis of alleged degrees of culpability.

Finally, while commenters acknowledged OIG's experience in CMP enforcement as the main support for its degree-of-culpability proposal, commenters noted that this rule expands OIG's authority to new types of conduct under the five new ACA liability bases to its enforcement

authority. These additional bases for CMPs require physicians to understand new authorities and also expands OIG scienter determinations to new areas of the law. Given this expanded scope, commenters urged OIG to reconsider use of this new aggravating factor, especially without providing more detailed guidance distinguishing different mental standards and their applicability to CMPs, assessments, and exclusions.

Response: We have altered the final rule so that in cases in which the scienter standard required to prove a violation is lower than actual knowledge, having actual knowledge will be an aggravating factor. We will continue evaluating each case to determine the appropriate penalties and assessments and whether exclusion is appropriate. In any case in which the scienter standard required to prove a violation is lower than actual knowledge, actual knowledge is more egregious. The OIG's existing regulations provide that actual knowledge is an aggravating factor where a respondent knew an item or service was not provided as claimed or if the respondent knew that a claim was false or fraudulent. In the final rule, OIG is simply extending actual knowledge as an aggravating factor to all cases in which the scienter standard to prove a violation is lower than actual knowledge.

Comment: One commenter expressed concern about OIG's proposed provision that any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors are present. The commenter argued that this proposed change would tilt the balance in favor of the aggravating factors without due consideration to all of the circumstances in each case and could lead to uneven enforcement. The commenter also stated that this concern was compounded by OIG's other proposal to move away from separately listed aggravating factors to a more general, illustrative list of factors that the commenter argues could be applied more broadly. Finally, the commenter also stated that this proposal could discourage mitigating actions (*e.g.,* participating in the Self-Disclosure Protocol).

Response: We believe that the proposed rule accurately reflects the case-by-case analysis that OIG has historically done and that is conducted in the ALJ hearing process. Aggravating and mitigating circumstances require qualitative weighing of facts and circumstances and are, by their nature, dependent on the facts and circumstances present in the individual case. In this weighing process, it is possible to conclude that one aggravating circumstance should overweigh several mitigating circumstances because of the nature and circumstances of the case. As such, our proposal that any one aggravating circumstance may justify a high penalty or assessment simply reflects this qualitative, fact-driven analysis. The converse is also true, that one mitigating factor could justify a lower penalty. Our proposal is not intended to change OIG's longstanding and repeatedly stated position that appropriate self-disclosure is a critical indication that the provider or supplier has an effective compliance program. We will continue to follow the process outlined in the Self-Disclosure Protocol in resolving Protocol submissions.

Comment: One commenter stated that proposed § 1003.140(d), which provides that OIG should exclude where there are aggravating circumstances, is superfluous because OIG already has the authority to exclude where aggravating circumstances exist. The commenter expressed concern that, if read so as not to be superfluous, the provision would suggest that exclusion is mandated by the rule.

Response: We agree with the commenter that the provision is superfluous. The OIG makes determinations regarding penalties, assessments, and exclusion based on a case-by-case analysis, and for any particular case the presence of aggravating circumstances may support exclusion. Therefore, we are finalizing the rule without this proposed provision.

Comment: A few commenters suggested that a lower level of intent be considered as a mitigating factor. Commenters argued that if a higher level of intent may be viewed as a potential aggravating factor, OIG should consider a lower level of intent as a mitigating factor.

Response: Possessing a lower level intent to commit a violation is not a defense against liability or a justification for a less serious remedy. Individuals and entities are expected to know the law and Federal health care program rules. While the degree of culpability is relevant in our determination to impose a monetary or exclusion remedy, other factors, such as the nature and circumstances of the violation, may justify a maximum monetary remedy or exclusion to protect the Federal health care programs and beneficiaries. Moreover, if the facts show that the person did not possess the requisite level of intent to violate a particular statutory or regulatory provision, no monetary penalty or exclusion would apply.

Comment: Several commenters suggested that OIG expand the corrective action that would be considered as a mitigating factor to include more than submissions to the Self-Disclosure Protocol. Commenters argued that limiting the mitigating factor to use of the Self-Disclosure Protocol is overly limited and suggested that the following actions be considered mitigating: Disclosure to the CMS Self-Referral Disclosure Protocol, returning payments to Medicare contractors, internal investigation, and staff retraining. Commenters argued that retaining existing regulatory language, which more generally references corrective steps taken promptly after a problem was discovered, would allow providers and suppliers the flexibility to take the corrective action best fitted to their particular practice settings and is more likely to encourage providers and suppliers to actively take appropriate corrective action.

Response: We have decided to amend our proposal to include use of the CMS Self-Referral Disclosure Protocol (SRDP) as meeting the corrective action requirement for the mitigating factor. We decided to make this change to clarify that appropriately using the SRDP satisfies OIG's goals of encouraging disclosure and recognizes the specific protocol that CMS has created to handle physician self-referral law (Stark Law) compliance issues. Because conduct that implicates only the Stark Law is not eligible for OIG's Self-Disclosure Protocol, we wanted to clarify that using the SRDP for this conduct is appropriate. We do not believe the other actions described above are appropriate for this mitigating factor. Returning overpayments to the appropriate contractor is important. However, this action does not address or eliminate CMP liability if it exists. Put another way, if the conduct involves only overpayments and no CMP liability, there is no penalty at issue to mitigate. Similarly, taking actions such as internal investigations and retraining employees can be important compliance program activities. However, in the absence of a self-disclosure, these actions also do not affect CMP liability.

We are also amending subpart E (EMTALA) to include in this mitigating factor disclosure of the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

Comment: Some commenters stated that, as a practical matter, this proposal

''mandates'' disclosure to the Protocol, which would, for many providers and suppliers, limit the availability of this mitigating circumstance. Some commenters viewed participation in the Protocol as time and labor intensive and often necessitating the assistance of an experienced attorney, which may be expensive for smaller providers and suppliers.

Response: This mitigating factor becomes relevant only if the provider or supplier has CMP liability for the conduct at issue. If that is the case, we expect the provider or supplier to appropriately disclose and resolve the conduct in the Protocol. Attorney representation is not necessary to use the Protocol.

Comment: Some commenters posed questions concerning the relationship between the Self-Disclosure Protocol and the proposed rule. For example, the Self-Disclosure Protocol states that ''OIG's general practice is to require a minimum multiplier of 1.5 times the single damages'' while the proposed rule contains no discussion concerning the nexus between Protocol settlements and the imposition of monetary penalties, assessments, and exclusion. Commenters asked whether the 1.5 multiplier will be available to those using the Self-Disclosure Protocol if an aggravating factor exists under the proposed rule. Commenters also asked whether OIG would suspend the statutory obligation to report and return an overpayment within 60 days if the provider has appropriately made a disclosure under the Self-Disclosure Protocol and is actively seeking a resolution.

Response: The OIG will continue to follow the process and principles outlined in the Self-Disclosure Protocol in resolving Protocol submissions. Even where aggravating circumstances exist, we will generally apply a 1.5 multiplier in Protocol resolutions, as explained in the Protocol. Regarding the 60-day rule referenced by commenters, CMS has rulemaking authority concerning section 1128J(d) of the Act and published a final rule on February 12, 2016. 81 FR 7654 (February 12, 2016). The regulation adopted by that final rule states: ''The deadline for returning overpayments will be suspended when the following occurs: (i) The OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.'' 42 CFR 401.305(b)(2)(i).

Comment: Some commenters expressed concerns about the proposed rule's expansion of the ''history of prior offenses'' and ''other wrongful conduct'' aggravating factors. Specifically, these commenters argued that it would be unjust to consider prior offenses or other wrongful conduct of officers or managing employees unless the officer or managing employee knew or should have known of the violation. Accordingly, they urged OIG to, as with individuals with ownership or control interests, limit consideration of prior offenses and other wrongful conduct of officers and managing employees to situations in which the officer or managing employee knew or should have known of the violation.

Response: We are finalizing the rule, as proposed. Officers and managing employees have significant responsibility for an entity's day-to-day operations. Owners, on the other hand, may be active or passive. Passive owners may have less involvement in daily operations, and consequently may have less culpability in the entity's conduct that creates CMP liability. As such, the rule specifies that individuals who have a direct or indirect ownership or control interest are considered in these factors only if they knew or should have known of the violation. Moreover, this factor was structured to reflect the exclusion authority under section 1128(b)(15) of the Act. Under section 1128(b)(15)(A)(ii) of the Act, an individual who is an officer or managing employee of an excluded entity can be excluded regardless of whether the officer or managing employee knew or should of known of the action that constituted the basis for the exclusion. In contrast, under section 1128(b)(15)(A)(i) of the Act, an owner of the excluded entity can be excluded only if he or she knew or should have known of the action constituting the basis for the exclusion. We believe that Congress intended this different treatment to account for the greater responsibility of officers or managing employees in the entity's day-to-day operations.

Comment: One commenter argued that ''administrative sanctions'' in the ''history of prior offenses'' aggravating factor should not include actions taken by purely private actors, such as health insurers, because, in such private actions, health care providers may not be given due process protections comparable to those available when a governmental entity is seeking administrative sanctions.

Response: We agree with the commenter that the history of prior offenses aggravating factor encompasses only situations in which the provider or supplier was held liable for criminal, civil, or administrative sanctions by a governmental entity, such as a Federal or State agency or one of its contractors.

Comment: One commenter expressed concerns with the proposed rule's increased consideration of wrongful conduct related to the commercial market. The commenter recommended that OIG consider only *fraud* sanctions in the private market to ensure that the wrongful conduct directly relates to the conduct being addressed by OIG.

Response: We are finalizing the language, as proposed. We do not believe the other wrongful conduct needs, in all cases, to be related to fraud generally or to the CMP authority at issue to be relevant. This factor is intended to provide some guidance on the trustworthiness of the individual or entity in question. The OIG will continue to perform an analysis of whether the other wrongful conduct should be considered an aggravating circumstance in any given case.

1003.150 Delegation of Authority

The proposed rule also adds an express delegation of authority from the Secretary to OIG to impose penalties, assessments, and exclusions against persons who violate any of the provisions of part 1003. Several **Federal Register** notices and delegation letters, spanning more than 20 years, delegate various authorities to OIG. Some of these older notices and letters are no longer easily accessible by the public, such as 53 FR 12,993 (April 20, 1988). This provision, at proposed § 1003.150, reiterates OIG's authority to pursue these matters.

We received no comments on this provision and finalize, as proposed.

1003.160 Waiver of Exclusion

We also proposed changes to part 1003's exclusion-waiver provisions to clarify the criteria for a waiver request from a State agency. The existing regulations stated that OIG will consider an exclusion waiver request from a State agency for exclusions imposed pursuant to 42 CFR 1003.102(a), (b)(1), and (b)(4) and 1003.105(a)(1)(ii) under certain circumstances. We proposed updating the regulations to permit an administrator of a Federal health care program to request a waiver, similar to the waiver in part 1001. Also, we proposed removing the limitations concerning when a waiver may be requested by such an administrator.

We received no comments on this provision and finalize, as proposed.

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Subpart B contains most of the provisions that were found in the existing regulations at § 1003.102(a) and several of the provisions that were found in § 1003.102(b). The text of the proposed provisions remains largely unchanged, except for a separate provision we created to address section 1128A(a)(6) of the Act. Section 1128A(a)(6) of the Act subjects persons to liability for arranging or contracting with (by employment or otherwise) a person who the employer or contractor knows or should know is excluded from participation in a Federal health care program for the provision of items or services for which payment may be made under that program. This authority was included in the regulations describing false or fraudulent claims at § 1003.102(a)(2). Because of our desire to improve the clarity of the regulations generally and because of the proposed penalty and assessment provisions discussed below, the proposed regulation addressed section 1128A(a)(6) of the Act in a separate subsection at § 1003.200(b)(4).

On the basis of our experience enforcing section 1128A(a)(6) of the Act, we proposed an alternate methodology for calculating penalties and assessments. This alternate methodology recognizes the variety of ways in which items and services are reimbursed by Federal health care programs and the numerous types of health care professionals and other individuals and entities that contribute to the provision of those items and services.

The proposed regulations addressed how penalties and assessments would be imposed for two distinct types of violations: (1) Instances in which items or services provided by the excluded person may be separately billed to the Federal health care programs and (2) instances in which the items or services provided by the excluded person are not separately billable to the Federal health care programs, but are reimbursed by the Federal health care programs in some manner.

To achieve this distinction, we proposed to define two new terms: ''separately billable item or service'' and ''non-separately-billable item or service.'' A ''separately billable item or service'' is defined as ''an item or service for which an identifiable payment may be made under a Federal health care program.'' This type of item or service exists when a person provides, furnishes, orders, or prescribes an identifiable item or service for which a claim for reimbursement may be submitted to a Federal health care program by either the person or another person. Examples include physician office visits and prescribed pharmaceuticals.

A ''non-separately-billable item or service'' is defined as ''an item or service that is a component of, or otherwise contributes to the provision of, an item or service, but is not itself a separately billable item or service.'' Non-separately-billable items or services are reimbursed as part of the claim submitted under the applicable payment methodology, *e.g.,* nursing or clerical services associated with a physician office visit, care covered by the skilled nursing facility per diem payment, nursing care covered by a hospital diagnosis-related group (DRG) payment, or radiology technician services associated with a specific procedure.

In instances in which the item or service provided by the excluded person is separately billable, the employing or contracting person would continue to be subject to penalties and assessments based on the number and value of those separately billable items and services. For instances in which the item or service provided by the excluded person is non-separately-billable, we proposed an alternate methodology to calculate penalties and assessments. We proposed that penalties would be based on the number of days the excluded person was employed, was contracted with, or otherwise arranged to provide non-separately-billable items or services. We proposed that assessments would be based on the total costs to the employer or contractor of employing or contracting with the excluded person during the exclusion, including salary, benefits, and other money or items of value. We believe this cost-based assessment achieves the purposes of section 1128A(a)(6) of the Act by capturing the value of the excluded person to the employing or contracting person. As discussed below in our response to comments, we are finalizing the assessments, as proposed, but are finalizing the penalties based on each item or service provided by the excluded person.

As discussed above, the ACA added five new violations and corresponding penalties to the CMPL. These new violations and the corresponding penalties are at proposed §§ 1003.200(b)(6)–(10), 1003.210(a)(6)–(9), and 1003.210(b)(3). In general, the proposed regulatory text closely mirrors the statutory text. However, we supplement the statutory text where appropriate. Section 6402(d)(2)(A) of the ACA amends the CMPL by adding a violation for knowingly making or causing to be made ''any false statement, *omission,* or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program.'' (Emphasis added.) ACA does not, however, include the word ''omission'' in its description of the penalty and assessment for this violation. To give full effect to the amendment adding ''omission'' to the CMPL, we have added the word ''omission'' in the penalty and assessment sections.

Also, we proposed clarifying the penalty under the CMPL, as amended by section 6402(d)(2) of the ACA, for failure to report and return overpayments. Under the amended section 1128J(d) of the Act, overpayments must be reported and returned by the later of 60 days after the date the overpayment was identified or the date any corresponding cost report is due, if applicable. The new CMPL authority under section 1128A(a)(10) of the Act does not contain a specific penalty amount, but instead uses the default penalty amount in the CMPL, which is up to $10,000 for each item or service. In this context, we proposed regulatory text interpreting the CMPL's default penalty as up to $10,000 for each day a person fails to report and return an overpayment by the deadline in section 1128J(d) of the Act. Because the failure to report and return overpayments within 60 days of identification is based on the 60-day period passing, we believed that the penalty could be interpreted to attach to each following day that the overpayment is retained. However, as we noted in the proposed rule, Congress specified a per day penalty in sections 1128A(a)(4) and (12) of the Act and did not do so for section 1128A(a)(10) of the Act. Thus, we solicited comments on whether to interpret the default penalty of up to $10,000 for each item or service as pertaining to each claim for which the provider or supplier identified an overpayment. As discussed below in our response to comments, we are finalizing the rule using the default penalty amount in the CMPL, which is up to $10,000 for each item or service.

Section 6408(a)(2) of the ACA amended the CMPL by adding a violation for failure to grant timely access, upon reasonable request, to OIG for the purpose of audits, investigations, evaluations, or other statutory functions. Section 1128(b)(12) of the Act and 42 CFR 1001.1301 authorize exclusion based on similar, but not identical, conduct — failure to grant immediate

access. We believe Congress expanded OIG's authority to exclude, and created an authority to impose a penalty, in a broader set of circumstances than covered by section 1128(b)(12) of the Act by using the phrase ''timely access'' in section 6408(a)(2) of the ACA. Thus, we believe conduct that implicates section 1128(b)(12) of the Act is a subset of the conduct implicated by the new CMPL authority created by section 6408(a)(2) of the ACA. In these situations, OIG has the discretion to choose whether to pursue exclusion under section 1128(b)(12) of the Act or penalties and/or exclusion under section 6408(a)(2) of the ACA. In drafting regulations pursuant to section 6408(a)(2) of the ACA, we evaluated the conduct covered by section 1128(b)(12) of the Act to ensure that this proposed rule is consistent with § 1001.1301.

The proposed definitions of ''failure to grant timely access'' and ''reasonable request'' give OIG flexibility to determine the period in which a person must respond to a specific request for access, depending on the circumstances. Given the different purposes for which OIG may request access to material, such as audits, evaluations, investigations, and enforcement actions, we believe the best approach is for OIG to specify the date for production or access to the material in OIG's written request. In making this decision, OIG will consider the circumstances of the request, including the volume of material, size and capabilities of the party subject to the request, and OIG's need for the material in a timely way to fulfill its responsibilities. The exception to this approach is a case in which OIG has reason to believe that the requested material is about to be altered or destroyed. Under those circumstances, timely access means access at the time the request is made. This exception is the same as provided in § 1001.1301.

Finally, we proposed revisions to the regulation's aggravating factors for CMPL violations. The aggravating factors listed in proposed § 1003.220 are based on those that apply to the violations in the existing regulations. We proposed moving the aggravating factors to one section and consolidating similar factors into one factor. For instance, the first aggravating factor, *i.e.,* the violations were of several types or occurred over a lengthy period, was found at § 1003.106(b)(1)(i). We interpret the phrase ''several types'' to include, but not be limited to, billing for services that are covered by different billing codes. The final aggravating factor relates to the amount or type of financial, ownership, or control interest, or the degree of responsibility a person has in an entity with respect to actions brought under § 1003.200(b)(3). While we will consider whether a person is a CEO or a manager, job titles alone will not guide our consideration of this factor; we will look at the degree of responsibility and influence that a person has in an entity.

We received the following comments on this subpart. To the extent provisions of the proposed rule are not addressed in the comments below, we are finalizing this section of the rule, as proposed.

Comment: We received many comments supporting the creation of the alternate methodology for calculating assessments for employing or contracting with an excluded individual in violation of section 1128A(a)(6) of the Act. Some commenters argued against a per-day penalty. First, commenters argued that the assessment adequately addresses the misconduct and a per-day penalty seems duplicative. Second, commenters argued that liability should be related to the cost of the items and services and may not be rationally related to the number of days an individual was employed by, or contracted with, the entity. Third, commenters argued that a per-day penalty is contrary to the plain language of the Act because Congress created other per-day penalties in the CMPL but did not create one in section 1128A(a)(6) of the Act. Finally, commenters maintained that the proposed method of calculating the assessment for contracting with or employing an excluded individual whose services are not separately billable to Federal health care programs already adequately takes into consideration the length of time of the prohibited relationship. A longer period of the prohibited relationship would result in more salary and benefits paid to the person, and thus would increase the value of the assessment.

Response: After considering the comments, we are withdrawing the proposed per-day penalty for section 1128A(a)(6) of the Act. Instead, we are finalizing a penalty of up to $10,000 for each item or service provided by the excluded person by removing proposed § 1003.210(a)(4)(ii) and adding ''non-separately billable'' items or services to proposed § 1003.210(a)(4)(i). This penalty more closely tracks the Act's language.

Comment: Many commenters urged OIG to take into account the Federal health care program payor mix, or percentage of Federal health care program business, when determining the assessment for employing or contracting with an excluded individual. Commenters argued that using a pro-rata share of the compensation would more fairly capture the portion of time the excluded person likely spent providing items or services to Federal health care program beneficiaries in violation of their exclusion. These commenters noted that OIG outlined this practice in the 2013 Updated Provider Self-Disclosure Protocol.

Response: We are finalizing the rule, as proposed. We continue to believe that the Federal health care program payor mix is appropriate to consider in the context of a self-disclosure, and OIG will continue to consider it in settlements, as appropriate. Nevertheless, we have decided not to require the consideration of payor mix in the regulations. The appropriate way to measure payor mix is not always clear for the many types of providers, suppliers, items, and services at issue in various cases. Further, there may be cases for which a reduction of the assessment based on payor mix is not appropriate. We view our approach to this CMP as analogous to the CMP for violations of the anti-kickback statute. Under § 1003.310(b)(2), OIG may seek damages of up to three times the amount of remuneration regardless of whether some of the remuneration was for a lawful purpose. Nevertheless, in self-disclosures and other settlements, we often collect a multiplier based only on the portion of the remuneration that we determine was for an unlawful purpose. We anticipate continuing a similar approach under this CMP authority.

Comment: Several commenters objected to our proposed reading of the penalty and assessment sections applicable to violations of section 1128A(a)(9) of the Act, as established by section 6402(d)(A) of the ACA, to include ''omissions.'' Those commenters argued that our reading went beyond the authority of the ACA because Congress did not include the term ''omissions'' in the penalty language.

Response: We respectfully disagree with the commenters. Adopting the commenters' suggested reading would lead to the conclusion that Congress intended to restrict OIG to pursuing an exclusion action only against those who omitted a material fact and intended to permit OIG to choose between pursuing penalties, assessments, and exclusions against those who made a false statement or misrepresentation of a material fact. This reading leads to an absurd result. Instead, we are interpreting this provision consistent with the purpose and intent of the statute.

Comment: Some commenters requested that OIG clarify that liability for omission of a material fact under Section 1128A(a)(9) of the Act apply only to willful omissions so that the regulations not capture clerical errors or omissions where there was no intention to deceive. Specifically, commenters encouraged us to delete the reference to ''omissions'' or at a minimum use the term ''willful omissions'' until a greater degree of standardization among Medicare contractors and their processes and interpretations is achieved. Commenters argued that the proposed definitions of ''knowingly'' and ''should know, or should have known'' where ''no proof of specific intent to defraud is required'' may result in a violation based on an error or oversight.

Response: We do not believe the commenters' suggestion conforms to the statute. To violate section 1128A(a)(9) of the Act, a person must knowingly make a false statement, omission, or misrepresentation of material fact. We believe the commenters' concerns are addressed by the evidentiary standard OIG must meet to bring such a case. In addition, OIG will continue to evaluate the nature and circumstances of the conduct and exercise discretion in deciding whether to pursue a case. The OIG will not pursue cases under this section based on inadvertent (non-reckless) errors and minor oversights.

Comment: Some commenters urged OIG to further specify the standards it will use to determine penalties, assessments, or exclusion imposed under section 1128A(a)(9) of the Act. Commenters stated that clarification is needed to understand whether this new authority could apply to simple documentation errors. Commenters believed that such mistakes would not be done ''knowingly.'' According to commenters, documentation errors are common—not because of deliberate physician misrepresentation, but because of frequent changes in the requirements for applications, contracts, and other agreements that may lead to confusion and miscommunications.

Response: We do not believe further guidance is appropriate in this context. We are unable to anticipate all potential factual scenarios in this rulemaking. We believe our traditional evaluation of the nature and circumstances of the conduct and exercise of discretion will inform whether to pursue an individual enforcement action. As previously stated, it is not OIG's intention to pursue cases under this section for inadvertent (non-reckless) errors or minor oversights.

Comment: One commenter stated that the $50,000 penalty amount set forth in § 1003.210(a)(6) for knowingly making a false statement, omission, or misrepresentation of a material fact seemed excessive, and should be reconsidered by OIG and that, if levying a heavy penalty is authorized, the application should be as narrow and temperate as possible.

Response: The penalty amount is statutory. We will continue to engage in our traditional evaluation of the nature and circumstances of the conduct and exercise of discretion in deciding to pursue cases and determine appropriate penalty amounts.

Comment: Many commenters disagreed with our proposed per-day penalty for failure to report and return an overpayment in violation of section 1128A(a)(10) of the Act. Commenters noted that Congress has created per-day penalties for two different sections of section 1128A of the Act and did not do so here. One of these two sections, failure to grant timely access to OIG, was enacted as part of the ACA, in which the overpayment authority was also enacted. The commenters argued that if Congress had intended to create a per-day penalty for section 1128A(a)(10) of the Act, it would have expressly done so in the ACA. In addition, some commenters stated that a per-day approach could lead to large penalties that may not be commensurate with the value of the underlying overpayment. Most commenters asserted that the penalty for overpayments should be the CMPL's default penalty of up to $10,000 for each item or service. Some commenters recommended a per-claim penalty calculation, rather than a per-day or per item or service calculation. Other commenters argued OIG should consider the lateness and size of overpayment in determining the penalty amount.

Response: After careful consideration, we are finalizing the penalty for section 1128A(a)(10) of the Act as up to $10,000 for each item or service. This penalty methodology is the statutory default. Where a person fails to return the overpayment for a lengthy period, the general aggravating factor under § 1003.220(b)(1) could be triggered.

Comment: Some commenters encouraged OIG to adopt a penalty scale for violations of section 1128A(a)(10) of the Act that would penalize providers more gravely for more serious violations. Commenters suggest that such a scale could be based on the length of delay, overpayment amount, and the number of claims.

Response: The factors set forth in § 1003.140 and § 1003.220 provide a framework to identify more egregious conduct and determine appropriate penalty amounts. The general factor of nature and circumstances would naturally take into account such factors as the length of time the provider or supplier knew it had received an overpayment and § 1003.220 states that an overpayment in an amount over $50,000 may be considered as an aggravating circumstance.

Comment: Commenters from pharmacy organizations expressed concerns with the proposed penalty under section 1128A(a)(10) of the Act of $10,000 per day for each ''claim.'' Commenters argued that the proposed rule would affect pharmacies more than other providers because pharmacies dispense billions of low-cost medications each year and, therefore, any potential penalty would be disproportional to the injury caused. Instead of a $10,000 penalty on each prescription, the commenters suggested that OIG examine other alternatives for calculating a penalty for pharmacies and other entities that submit many small ''claims.'' Examples of potential solutions include calculating the penalty at $10,000 per day regardless of the number of individual prescription claims involved, or assessing a penalty in proportion to the overall dollar amount of the overpayment.

Response: Based on our evaluation of all the comments on this issue, we are finalizing the penalty as up to $10,000 for each item or service. In the case of pharmacies, each prescription would be considered an item, and thus pharmacies have exposure of up to $10,000 for each prescription for which the pharmacy received an overpayment. This is the result compelled by the statute. We will evaluate the facts and circumstances in each case to determine the appropriate penalty amount.

Comment: Some commenters from Part D plan sponsors expressed concerns about the use of per-day, per-claim, or per-item or service penalties in the context of Part D prescription drug claims. Given the huge volume of daily prescription drug events (PDEs), which are not equivalent to final medical claims, commenters believed that the application of CMPs in Part D should focus on the ''annual cost report'' and not on individual PDEs. According to commenters, Part D drug claims are not final until both the annual reconciliation and the final reopening are completed. Commenters recommended that OIG clarify that, in the context of Part D, determination of the penalty amount should be based on

the ''annual cost report'' submitted by Part D sponsors and not on individual PDEs. Further, commenters argued that OIG should clarify that a PDE is not a claim until it has gone through reconciliation and the final reopening has been completed.

Response: We are finalizing the penalty for section 1128A(a)(10) of the Act, using the CMPL default of up to $10,000 for each item or service. This penalty is consistent with the final rule adopted by CMS regarding Part D overpayments. *See* 79 FR 29,844. In adopting that rule, CMS declined to make the deadline for reporting and returning identified overpayments the ''date any corresponding cost report is due'' because ''Part D sponsors are paid based on their bids, and not based on their actual incurred costs.'' 79 FR at 29,920. In determining an overpayment, CMS focuses on the submission of erroneous PDE data, and those data constitute claims for items or services under the CMPL.

Comment: Some commenters suggested that OIG does not recognize CMS's role in overseeing section 1128J of the Act, as applicable to Part C plans or Part D plan sponsors, pursuant to 42 CFR 422.326 and 423.360. One commenter suggested that OIG defer to CMS on overpayment issues and reserve its authority for instances of egregious behavior.

Response: While CMS oversees Part C plans and Part D plan sponsors under its regulations, OIG has been delegated the authority for enforcement of section 1128A of the Act. Thus, we decline to adopt the commenter's suggestion.

Comment: Several commenters suggested that for Part C plans and Part D plan sponsors, compliance with CMS's final rule, 79 FR 29,844 (May 23, 2014), should be deemed compliance with section 1128A(a)(10) of the Act. Specifically, commenters recited the language of that final rule and stated that a Medicare Advantage organization has identified an overpayment when that organization has determined, or should have determined through the exercise of reasonable diligence, that it has received an overpayment. Commenters stated that the phrase ''or should have determined through the exercise of reasonable diligence'' has caused great concern among health plans because there is no guidance for plans to follow and plans are exposed to potential FCA liability if they do not comply. According to commenters, this lack of clarity means that plans can act in good faith but still be subject to liability if their actions are later found to not meet the ''reasonable diligence'' test. In light of these uncertainties regarding compliance with the Part C and Part D rule, commenters requested that OIG's rule clarify that compliance with such rule will be deemed compliance with OIG requirements.

Response: This suggestion is outside the scope of our rulemaking, which did not propose to interpret the CMS final rule concerning Part C plans and Part D plan sponsors. In the context of section 1128A(a)(10) of the Act, a plan or plan sponsor may be liable if it knows of an overpayment and did not report and return it in accordance with section 1128J of the Act.

Comment: Several commenters asked that OIG clarify the definition of ''overpayment.'' One commenter suggested that OIG should use CMS's definition of ''funds'' in the Part C and D final rule, 79 FR 29,844 (May 23, 2014). One commenter also asked that we clarify the application of section 1128A(a)(10) of the Act in situations in which the plan is not at fault for the overpayment, such as when CMS makes a retroactive change to a member's low-income status that triggers changes in the low-income subsidy payments for cost sharing and premiums or affects the coverage gap discount program.

Response: We are finalizing the definition, as proposed. The proposed regulatory text simply mirrors the statute. In the context of Parts C and D, CMS has interpreted the meaning of ''overpayment,'' and we are required to apply the same meaning in an enforcement action against a Part C plan or Part D plan sponsor under section 1128A(a)(10) of the Act. This regulation also applies to Medicare Parts A and B and to Medicaid, so we believe the overpayment definition in our regulations should be broad enough to cover all of the programs. Commenters' other suggestions are outside the scope of this rulemaking. Plans should refer to CMS's May 2014 final rule, 79 FR 29,844 (May 23, 2014), in self-assessing their compliance with reporting and returning overpayments.

Comment: Several commenters requested clarification as to when the 60-day period begins. Commenters also requested clarification of the term ''identify.'' Some commenters suggested that OIG not impose CMPs for overpayments, or alternatively, defer issuance of this final rule, until CMS finalizes its Part A/B overpayment proposed rule, 77 FR 9179 (February 16, 2012), which, among other things, defines when an overpayment has been identified. A few commenters suggested that OIG use the term ''confirmed'' rather than ''identify'' because some providers and suppliers have complex billing processes that require coordination with other providers and suppliers. For example, for air ambulances, additional information and documentation are needed from other providers to determine the correct amount of an overpayment. Commenters encouraged OIG to include in the final rule a clear standard as to when the 60-day period begins and to exercise discretion in enforcing this authority so that providers and suppliers are not harshly penalized when good faith efforts to meet the 60-day rule are made but delays occur because of the action or inaction of entities beyond the providers' or suppliers' control.

Response: We will continue to evaluate the nature and circumstances of the conduct and the exercise of discretion when deciding whether to pursue a case. The obligations of section 1128J(d) of the Act became effective upon enactment, without a final rule from CMS. However, CMS published its final rule on February 12, 2016. 81 FR 7654 (February 12, 2016). The comments asking OIG to defer issuance of its final rule are therefore moot. We do not in this regulation provide definitions for or clarify the meaning of ''identify'' or clarify when the 60-day period begins. These topics are within CMS's purview and are included in its final rule. 81 FR at 7683.

Comment: Some commenters stated that providers should not be penalized under section 1128A(a)(10) of the Act in cases in which good faith efforts to return overpayments could not be completed because of the inability of government contractors and their payment systems to receive the overpayment. The commenters complained that Medicare, Medicaid, and Medicaid managed care organizations (Medicaid MCOs) have payment process systems that can both cause overpayments and that can prevent providers from promptly returning overpayments. The commenters contended that when a provider discovers an overpayment and attempts to return it to a Medicaid MCO, if the Medicaid MCO has not yet corrected the system error that led to the overpayment, the Medicaid MCO may be unable accept the returned overpayment. The commenters argue that this leaves the provider with no avenue for the prompt return on the overpayment.

Response: As stated above, CMS is responsible for issuing regulations concerning section 1128J(d) of the Act and, thus, these comments are outside the scope of this rulemaking. As they relate to OIG's enforcement of section 1128A(a)(10) of the Act, we will consider the nature and circumstances

of each alleged violation in determining whether to bring an enforcement action and at what amount to set the penalty and assessment. In situations in which a person attempts to return an overpayment but a Medicare contractor, Medicaid, or a Medicaid MCO rejects the returned overpayment at no fault of the person, it is unlikely that OIG would pursue an action.

Comment: One commenter suggested that, when OIG begins imposing CMPs under section 1128A(a)(10) of the Act, OIG should impose CMPs of not more than $5,000 until OIG has more experience analyzing violations of that section.

Response: We respectfully disagree with the commenter's suggestion. The obligations under section 1128J(d) have been in effect since the statute was enacted in March 2010. As with all other cases, OIG will determine the amount of the penalty and assessment pursuant to the criteria set forth in § 1003.140 and § 1003.220.

Comment: Several commenters suggested that OIG exercise its authority under section 1128A(a)(10) of the Act in coordination with CMS to ensure that: (1) Providers' obligations are uniform across these agencies; and (2) actions by OIG and CMS are undertaken contemporaneously to ensure that the associated administrative burden on providers is minimized.

Response: The OIG coordinates regularly with CMS on various program integrity efforts, including, as appropriate, on OIG administrative enforcement actions. As with many Medicare and Medicaid subject areas, CMS issues regulations on the 60-day repayment rule in section 1128J(d) and OIG is authorized to pursue administrative sanctions against those that violate the rule. However, as set forth in § 1003.150, we have been delegated the enforcement responsibility for section 1128A(a)(10) of the Act.

Comment: Two commenters requested that we clarify that penalties for violation of section 1128A(a)(10) of the Act set forth in the rule are the maximum allowed, leaving discretion to OIG to levy smaller penalties, or no penalties, in cases in which providers are acting in good faith or the delays in repayment are beyond the control of the provider.

Response: We believe that the proposed rule's language, which we are finalizing, is clear on this point. All penalties in the proposed rule are described as ''not more than'' the applicable penalty amount.

Comment: Several commenters requested that OIG clarify that the CMP at § 1003.200(b)(6), regarding excluded persons who order or prescribe an item or service that will be paid for by a Federal health care program, applies only to the excluded person and not to the person who provides the service. Some of these commenters mentioned the example of an air ambulance provider who, as an emergency responder, responds only at the request of physicians to transport a patient to a different facility, or when called to an accident scene by the Emergency Medical System or other qualified dispatcher. In such an emergent situation, commenters stated it is nearly impossible for transport providers to know the exclusion status of those who ordered or prescribed the transport. One commenter acknowledged that the service itself will likely be considered non-covered, which would result in the provider having received an overpayment, but argued that the imposition of a CMP in addition to the overpayment would be unduly harsh.

Response: We agree that, based on a plain reading of the statutory language, the CMP authority at § 1003.200(b)(6) would be imposed against the excluded person who ordered or prescribed the item or service, not against the person who provided or supplied the items or services that were ordered or prescribed. With regard to emergency services, section 1862 of the Act and § 1001.1901(c)(5) allow payment for emergency items or services not provided in an emergency room of a hospital in certain circumstances. Also, under section 1862 of the Act and § 1001.1901, items and services ordered or prescribed by an excluded person are not payable only if the person furnishing such item or service knew or had reason to know of the exclusion.

Comment: Some emergency transport providers requested clarification that an emergency transport provider would not violate section 1128A(a)(1)(B) of the Act or § 1003.200(a)(2) for presenting a false or fraudulent claim when it relies upon a facially valid order to provide services. According to commenters, because of the emergency situation, there is little time to check the exclusion status of the ordering physician and no ability to refuse to provide the emergency services. Commenters recommended adding specific language to the regulations stating that, in the case of emergency services or transport, the provider or supplier would not be held liable for knowingly presenting such a claim if the ordering or prescribing physician was excluded.

Response: We decline to adopt the commenters' recommendation. If the provider or supplier knew or had reason to know that the ordering physician was excluded, the provider or supplier also knew or should have known that the claim for those emergency services is not payable. Submitting that claim could subject the provider or supplier to liability under § 1003.200(a)(2). In our experience, we have not seen a case in which an air ambulance provider submitted claims for emergency transportation ordered by an excluded individual and we believe such circumstances would be rare. We will continue to evaluate cases individually and use our discretion in determining which cases to pursue.

Comment: Several commenters expressed concern about the aggravating factor at § 1003.220(b)(3) relating to the amount of program loss. Specifically, the commenters suggested that OIG continue to use the ''substantial loss'' threshold in applying this aggravating factor instead of the proposed ''$15,000 or more'' threshold. The commenters viewed $15,000 as relatively low and argued that it would unfairly apply more often to providers who bill for expensive items or services. The commenters asserted that a specific overpayment threshold may have no correlation to the number of claims in error or the significance of the issue giving rise to the overpayment, and argued that it should not automatically be considered an aggravating factor in determining the amount of penalties and assessments levied against the provider. Therefore, these commenters suggested that OIG maintain the flexibility to determine, on a case-by-case basis, what is a ''substantial loss.'' Other commenters agreed with the proposal to change ''substantial loss'' to ''$15,000 or more'' because it provided transparency and better guidance to the provider community.

Response: We believe that a specific dollar threshold gives clearer guidance to the provider and supplier community and still permits the traditional case-by-case analysis of the facts and circumstances as discussed above. We agree, however, with those commenters who stated that the proposed $15,000 threshold is low. We have, instead, raised the ''substantial loss'' threshold to $50,000. Based on our experience resolving health care fraud matters, we believe $50,000 better reflects the threshold amount of loss for when a penalty or period of exclusion should be increased.

Comment: Some commenters opposed the proposed change to the aggravating factor in proposed § 1003.220(b)(4), which would amend existing § 1003.106(b)(1)(iv) to include situations

in which the violation ''could have resulted'' in patient harm, premature discharge, or a need for additional services or subsequent hospital admission. These commenters complain that the ''could have resulted'' language requires OIG to establish only the *mere possibility* of harm, regardless of what actually occurred. Commenters believed that this change would vastly expand the application of this aggravating factor and urged OIG to retain the existing language at § 1003.106(b)(1)(iv).

Response: We are finalizing the rule, as proposed. The existing regulation requires proof that the violation actually caused patient harm, premature discharge, or a need for additional services or subsequent hospital admission. This formulation is overly constrained for several reasons. The CMP authorities in this part, as a general matter, aim to redress fraud on the Federal health care programs by recovering funds, protecting the programs and beneficiaries from untrustworthy providers and suppliers, and deterring improper conduct by others. Accordingly, it is highly relevant if the conduct put beneficiaries at risk of patient harm. The requirement that OIG prove causation does not conform to this aim.

Comment: Several commenters objected to the proposed definition of ''reasonable request'' with respect to § 1003.200(b)(10). Commenters asked OIG to add to the definition that a request is not reasonable unless the recipient has a reasonable period of time to respond, taking into account the recipient's resources, regular business hours, availability, the location of the records, and the complexity and scope of the request. Commenters also asked OIG to include an objective, minimum period for compliance, such as 2 weeks or 10 days. Some commenters suggested that OIG include an exception to that minimum period when there is a demonstrated need for a faster response. One commenter asked OIG to use discretion when a recipient of a request, acting in good faith, does not meet the specified timelines.

Response: We do not believe a minimum period is necessary or appropriate in this context. Given the different purposes for which OIG may request access to material, such as audits, evaluations, investigations, and enforcement actions, we believe the best approach to defining timely access and reasonable request is for OIG to specify the date for production or access to the material in a written request. In determining the period a provider has to comply with the request, OIG will consider the circumstances of the request, including the volume of material, size and capabilities of the party subject to the request, and OIG's need for the material in a timely way to fulfill its responsibilities. The exception to this approach is a case in which OIG has reason to believe that the requested material is about to be altered or destroyed. Under those circumstances, timely access means access at the time the request is made.

Comment: Some commenters noted that a ''reasonable request'' must be ''made by a properly identified agent of OIG during reasonable business hours,'' but that the definition does not specify whether it refers to OIG's or the recipient's business hours. Commenters urged OIG to clarify that the request must be made during the recipient's regular business hours and when the recipient's office is open to the public.

Response: ''Reasonable business hours'' means the recipient's business hours. This time includes when the recipient holds itself out to the public as open, such as for appointments or walk-in customers. However, a recipient may also conduct its business outside of the times when it is open to the public. We are finalizing the definition, as proposed.

Comment: One commenter expressed concern about OIG's authority to exclude a provider under § 1003.200(b)(10), asserting that OIG requests for information could get lost among other mail in light of the number of entities that request medical documentation from providers to validate services and payment. The commenter asked that a single, recognizable standard be put in place to clearly identify a request from OIG or any other auditing entity.

Response: We do not believe that such a single standard needs to be put in place. The OIG requests for information are clearly identifiable as being from OIG. The requests are made in writing, appear on OIG letterhead, and are signed by OIG officials.

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

Subpart C contains the provisions relating to violations of the anti-kickback statute and physician self-referral law, which were found in the existing regulations at § 1003.102(a)(5), (b)(9), (b)(10), and (b)(11). The proposed changes include various technical corrections to improve readability and ensure consistency with the language in the anti-kickback statute and physician self-referral law.

We proposed revising the CMP provisions relating to the physician self-referral law to incorporate statutory terms that are unique to the physician self-referral law (section 1877 of the Act (42 U.S.C. 1395nn)). These revisions include using ''designated health service'' instead of ''item or service'' and ''furnished'' instead of ''provided.'' In addition, we proposed revising the authority regarding ''cross-referral arrangements'' that was in the existing regulations at § 1003.102(b)(10) to more closely reflect the statutory language. Section 1877(g)(4) of the Act provides for CMPs and exclusion against any physician or other person who enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person who, if the physician directly made referrals to such person, would violate the prohibitions of 42 CFR 411.353. The regulations, at § 1003.102(b)(10)(i), contained an example of a cross-referral arrangement whereby the physician-owners of entity ''X'' refer to entity ''Y'' and the physician-owners of entity ''Y'' refer to entity ''X'' in violation of 42 CFR 411.353. While this is one example of a cross-referral arrangement, such arrangements and circumvention schemes can take a variety of forms. The proposed changes to the regulatory language more closely align the regulations to the statute to avoid any misinterpretation that § 1003.102(b)(10)(i) limited the conduct that circumvents the prohibitions of the physician self-referral law.

The proposed changes also include minor technical corrections to the CMPs related to the anti-kickback statute to improve consistency with the statute. First, we added the phrases ''to induce'' and ''in whole and in part'' to § 1003.300(d) to better mirror the statutory language of the anti-kickback statute. The proposed change also clarified that the CMP at section 1128A(a)(7) of the Act permits imposing a penalty for each offer, payment, solicitation, or receipt of remuneration and that each action constitutes a separate violation. In addition, we included the language from the CMPL stating that the calculation of the total remuneration for purposes of an assessment does not consider whether any portion of the remuneration had a lawful purpose.

We received no comments and finalize this subpart, as proposed, except that, for the reasons provided in response to comments to proposed § 1003.220(b)(3), we increased the threshold for the aggravating factor at

§ 1003.302(b)(3) from $15,000 to $50,000.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

Subpart D contains the proposed provisions for penalties and assessments against managed care organizations. We proposed several stylistic changes to the existing regulations at § 1003.103(f). We changed the verbs in this subpart from past tense to present tense to conform to the statutory authorities and many other regulations in this part. The proposed regulation also removes superfluous phrases, such as ''in addition to'' or ''in lieu of other remedies available under law.'' The proposed regulation replaced references to ''an individual or entity'' with ''a person'' because ''person'' is defined in the general section as an individual or entity. The proposed regulation also removes the phrase ''for each determination by CMS.'' The OIG may impose CMPs in addition to or in place of sanctions imposed by CMS under its authorities.

We also added to the regulations OIG's authority to impose CMPs against Medicare Advantage contracting organizations pursuant to section 1857(g)(1) of the Act and against Part D contracting organizations pursuant to section 1860D–12(b)(3) of the Act.

The ACA amended several provisions of the Act that apply to misconduct by Medicare Advantage or Part D contracting organizations. We included these provisions in the proposed regulations. We added the change in section 6408(b)(2)(C) of the ACA regarding assessing penalties against a Medicare Advantage or Part D contracting organization when its employees or agents, or any provider or supplier that contracts with it, violates section 1857 of the Act. We proposed to add the five new violations created in the ACA, and their corresponding penalties, at § 1003.400(c). We also proposed to include the new assessments, which are available for two of the five new violations, at § 1003.410(c). The proposed regulatory text closely mirrors that of the statute.

The violations in this subpart are grouped according to the contracting organizations to which they apply. For instance, § 1003.400(a) violations apply to all contracting organizations. Section 1003.400(b) violations apply to all Medicare contracting organizations, *i.e.,* those with contracts under sections 1857, 1860D–12, or 1876 of the Act. Section 1003.400(c) violations apply to Medicare Advantage and Part D contracting organizations, *i.e.,* those with contracts under sections 1857 or 1860D–12 of the Act. Section 1003.400(d) violations apply to Medicare Advantage contracting organizations, *i.e.,* those with contracts under section 1857 of the Act. Section 1003.400(e) violations apply to Medicaid contracting organizations, *i.e.,* those with contracts under section 1903(m) of the Act.

We also proposed to remove the definition of ''violation,'' which was found at § 1003.103(f)(6), because throughout this part, violation means each incident or act that violates the applicable CMP authority. We also proposed including aggravating circumstances to be used as guidelines for taking into account the factors listed in proposed § 1003.140. These aggravating circumstances are adapted from those listed in the existing regulations at §§ 1003.106(a)(5) and 1003.106(b)(1) and those published in the **Federal Register** in July 1994. 59 FR 36072 (July 15, 1994).

We received the following comments on the subpart. As discussed in response to the comments, we are finalizing this section of the rule as proposed.

Comment: One commenter argued that certain alleged violations of § 1003.410(d) by a contracting provider or supplier might not entirely be the responsibility of that provider and supplier, but rather the result of pressures from the Part C plans. The commenter asked that OIG not permit Part C plans to avoid responsibility under § 1003.410(d) through indemnity clauses in the plans' contracts with providers and suppliers.

Response: This comment is outside the scope of our rulemaking. The OIG does not have regulatory authority over the programmatic aspects of the Part C and Part D programs, which would include setting limitations on or requirements for contracting organizations' relationships with providers and suppliers. CMS has this programmatic authority, which includes, among many other things, implementing the provider indemnification limitations contained in section 1852 of the Act and at 42 CFR 422.212.

Comment: Two commenters expressed concern with the overlapping enforcement authority of OIG and CMS with regard to Part D contracting organizations. The commenters argued that this overlap could subject Part D contracting organizations to duplicative enforcement actions, multiple audits of the same activities, and potentially inconsistent standards and interpretations of regulatory requirements. The commenters recommended that CMS be the sole enforcement authority with respect to those areas for which OIG and CMS share jurisdiction, except in cases in which OIG's unique investigative authority is necessary to determine non-compliance. One commenter recommended that OIG state that compliance with the Part D requirements, when assessed by CMS, will be deemed to be compliance with OIG's enforcement authorities. The commenter argued that, if CMS has already performed audits and other oversight activity, there is no reason for OIG to duplicate this work.

Response: We do not agree with the comments. The OIG and CMS have concurrent jurisdiction in various matters concerning the Medicare program, including this area. CMS and OIG have internal mechanisms in place to ensure that the other agency within the Department is not simultaneously pursuing a CMP for the same or similar conduct. The OIG will continue to coordinate appropriately with CMS on potentially overlapping CMP enforcement actions.

Comment: A commenter requested a change in the new authority at § 1003.400(b)(2) relating to employing or contracting with an excluded person for the provision of health care, utilization review, medical social work, or administrative services, or employing or contracting with an entity for the provision of such services directly or indirectly through an excluded person. Specifically, the commenter requested that a plan's liability cease with its employees and direct contractors and not extend to the employees or contractors of its contractor, whether a health care provider or otherwise. The commenter accordingly requested that OIG revise § 1003.400(b)(2) by striking the text after the term ''administrative services.'' To support this recommendation, the commenter noted that plans contract with numerous providers, including health systems, that, in turn, employ or contract vast numbers of persons. The commenter argued that plans would not be able to identify all of the individuals that a health system employs nor the persons with which a health system contracts.

Response: The proposed regulation mirrors the statutory language. Specifically, the ACA created a cause of action against a contracting organization that employs or contracts with an excluded person for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person. Accordingly, we are

finalizing this section of the rule, as proposed.

Comment: A commenter also asserted that OIG's proposed reference to ''health care, utilization review, medical social work, or administrative services'' is overly broad and asked OIG to revise ''administrative services'' to ''administrative services for a Medicare or Medicaid eligible individual.''

Response: We believe that the commenter's proposed revision is inappropriately narrow and does not reflect the statutory language. The regulation mirrors the language of the ACA. Second, there may be administrative services related to a Federal health care program that are not for a specific Medicare- or Medicaid-eligible individual.

Comment: A commenter requested clarification on the potential liability of plans for claims submitted by out-of-network providers or suppliers who have no privity of contract with the health plan.

Response: The CMP authority at § 1003.400(b)(2) does not apply to out-of-network providers or suppliers because the plan did not employ or contract with that person.

Subpart E—CMPs and Exclusions for EMTALA Violations

Subpart E contains the penalty and exclusion provisions for violations of EMTALA, section 1867 of the Act (42 U.S.C. 1395dd). EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272. Section 1867 of the Act sets forth the obligations of a Medicare-participating hospital to provide medical screening examinations to individuals who come to the hospital's emergency department and request examination or treatment for a medical condition. EMTALA further provides that, if the individual has an emergency medical condition, the hospital is obligated to stabilize that condition or to arrange for an appropriate transfer to another medical facility where stabilizing treatment can be provided. EMTALA also requires hospitals with specialized capabilities or facilities to accept appropriate transfers of individuals from other hospitals. Finally, EMTALA creates obligations for physicians responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on call for the care of that individual. The CMS regulations related to section 1867 of the Act are found at 42 CFR 489.24.

Under section 1867(d) of the Act, participating hospitals and responsible physicians may be liable for CMPs of up to $50,000 ($25,000 for hospitals with fewer than 100 State-licensed and Medicare-certified beds) for each negligent violation of their respective EMTALA obligations. Responsible physicians are also subject to exclusion for committing a gross and flagrant or repeated violation of their EMTALA obligations. The OIG's regulations concerning the EMTALA CMPs and exclusion are at 42 CFR 1003.102(c), 103(e) and 106(a)(4) and (d).

We proposed several updates to the EMTALA CMP regulations. First, as part of our proposed general reorganization, we have included the EMTALA authorities within a separate subpart. Further, the proposed revision removed outdated references to the pre-1991 ''knowing'' scienter requirement. We also proposed minor revisions to emphasize that the CMP may be assessed for each violation of EMTALA and that all participating hospitals subject to EMTALA, including those with emergency departments and those with specialized capabilities or facilities, are subject to penalties.

We proposed revising the ''responsible physician'' definition to clarify that on-call physicians at any participating hospital subject to EMTALA, including the hospital to which the individual initially presented and the hospital with specialized capabilities or facilities that has received a request to accept an appropriate transfer, face potential CMP and exclusion liability under EMTALA.

Section 1867(d) of the Act provides that any physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including any physician on-call for the care of such an individual, and who negligently violates section 1867 of the Act may be penalized under section 1867(d)(1)(B) of the Act. The definition of ''responsible physician'' also provides for on-call physician liability. We proposed to revise the definition to clarify the circumstances when an on-call physician has EMTALA liability. An on-call physician who fails or refuses to appear within a reasonable time after such physician is requested to come to the hospital for examination, treatment, or transfer purposes is subject to EMTALA liability. This includes on-call physicians at the hospital where the individual presents initially and requests medical examination or treatment as well as on-call physicians at a hospital with specialized capabilities or facilities where the individual may need to be transferred. In addition, an on-call physician at the hospital with specialized capabilities or facilities may violate EMTALA by refusing to accept an appropriate transfer.

We also proposed revising the factors that were set forth in §§ 1003.106(a)(4) and (d) to improve clarity and better reflect OIG's enforcement policy. First, we proposed clarifying that the factors listed in proposed § 1003.520 will be used in making both CMP and exclusion determinations. Further, we proposed incorporating the general factors listed in § 1003.140 and provide additional guidance on the EMTALA subpart at proposed § 1003.520. Many of the factors that were in § 1003.106(a)(4) and (d) duplicate those general factors.

Finally, we examined the factors that were at § 1003.106(d) in light of our lengthy enforcement experience. Congress enacted EMTALA to ensure that individuals with emergency medical conditions are not denied essential lifesaving services. 131 Cong. Rec. S13904 (daily ed. Oct. 23, 1985) (statement of Sen. David Durenberger); H.R. Rep. No 99–241, pt. 1, at 27 (1986), reprinted 1986 U.S.C.C.A.N. 579, 605. In light of this statutory purpose, the circumstances surrounding the individual's presentment to a hospital are important to determinations about whether and to what extent a CMP or an exclusion is appropriate. Thus, the proposed regulations revised the factors to clarify that aggravating circumstances include: A request for proof of insurance or payment prior to screening or treating; patient harm, unnecessary risk of patient harm, premature discharge, or a need for additional services or subsequent hospital admission that resulted, or could have resulted, from the incident; and whether the individual presented with an emergency medical condition. While we removed the language at § 1003.106(a)(4), we consider these circumstances to be included in the general factors listed at proposed § 1003.140. Thus, while the proposed regulations do not state that OIG will consider ''other instances where the respondent failed to provide appropriate medical screening examination, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer,'' OIG will consider each of these failures when determining a penalty because they relate to a respondent's history.

We concluded that for several reasons, the mitigating factors should be removed. Because of the overall statutory purpose, the fact-specific nature of EMTALA violations, and the CMS certification process, the mitigating factors that were found at

§ 1003.106(d) are not useful in determining an appropriate penalty amount. For example, § 1003.106(d)(5) stated that it should be considered a mitigating circumstance if an individual presented a request for treatment but subsequently exhibited conduct that demonstrated a clear intent to leave the hospital voluntarily. In our enforcement activities, however, we have found situations in which the individual may have demonstrated a clear intent to leave because the hospital failed to properly screen the individual within a reasonable amount of time. We do not believe that in this circumstance, the hospital's penalty should be mitigated. Further, the factor at § 1003.106(d)(6)(A) in the existing regulation is not relevant to mitigation because developing and implementing a corrective action plan is a requirement of the CMS certification process following an investigation of an EMTALA violation. However, in response to comments discussed below, we have determined that certain corrective action could be mitigating. Specifically, it should be considered a mitigating circumstance if a hospital took appropriate and timely corrective action in response to the violation prior to CMS initiating an investigation. That corrective action must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

We will continue to evaluate the circumstances of each EMTALA referral to determine whether to exercise our discretion to pursue the violation and to determine the appropriate remedy.

We received the following comments on the subpart. To the extent the provisions of the proposed rule are not addressed in response to the comments below, we are finalizing this section of the rule, as proposed.

Comment: One commenter urged OIG to adopt a regulation that does not impose penalties where the violation of EMTALA is based only on negligence and not on willful conduct.

Response: The suggestion is beyond the scope of the proposed rule and does not reflect the statutory language, which sets the scienter level at negligence.

Comment: Several commenters addressed OIG's changes to the definition of ''responsible physician.'' One commenter requested that OIG clarify that it is not creating a new application of EMTALA to hospitals with specialized capabilities, but simply clarifying that on-call physicians at hospitals with specialized capabilities are considered ''responsible physicians.'' Another commenter asserted that OIG's revised definition is an expansion of EMTALA to physicians and on-call physicians who fail to accept an appropriate transfer. This commenter argued that the nondiscrimination provisions in section 1867(g) of the Act apply only to participating hospitals and do not create CMP liability for physicians at such hospitals. One commenter noted that assessing whether a responsible physician has neglected his or her responsibilities under EMTALA is a rigorous undertaking. The commenter said that the assessment should include more than whether the on-call physician showed up when called, but also whether the on-call physician was in the operating room when called or whether a community call arrangement existed. Finally, a commenter urged OIG to ensure that its enforcement against a ''responsible physician'' is consistent with the regulations and guidance promulgated by CMS.

Response: We are finalizing the rule, as proposed. In response to comments, we confirm that OIG is clarifying that on-call physicians at hospitals with specialized capabilities are considered ''responsible physicians.'' The OIG believes this is an appropriate reading of the statute and that the proposed regulation does not expand the application of EMTALA. The OIG recognizes that a determination of potential liability for an on-call physician is fact-intensive and takes into account factors that include a hospital's compliance with CMS regulations and guidance regarding the adoption of written policies governing on-call physicians and an on-call physician's compliance with such policies.

Comment: Several commenters discussed OIG's proposal to remove the mitigating factors related to EMTALA CMPs. Two commenters objected to the removal of the mitigating factor under which an individual presented a request for treatment but subsequently exhibited conduct that demonstrated a clear intent to leave the hospital voluntarily. Another commenter stated that removal of this mitigating factor would remove consideration of a hospital's or physician's attempts to comply with EMTALA's requirements where they were unable to do so because of patient conduct over which they had no control. Further, a commenter asserted that EMTALA is not violated when a patient leaves of his or her free will.

Response: We are finalizing the rule, as proposed. The OIG believes that the evaluation of whether an EMTALA violation occurred when the individual who presented for treatment left the hospital voluntarily is fact- and circumstance-specific. If no violation is found to have occurred, the lack of the former mitigating factor would be of no consequence. If a violation is found to have occurred, the patient's having left voluntarily should not be a mitigating circumstance.

Comment: A commenter stated that additional mitigating factors, including the implementation of appropriate policies, procedures, training and action against hospital personnel prior to a CMS investigation, are useful and fair factors to distinguish hospitals making good faith and effective efforts to address EMTALA violations.

Response: The OIG agrees and has added as a mitigating factor situations in which a hospital takes appropriate and timely corrective action in response to a violation. For purposes of this mitigating factor, corrective action must be completed prior to CMS initiating an investigation of the hospital for violations of EMTALA and must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

Comment: One commenter objected to the proposed removal of the term ''clearly'' from the existing regulation at § 1003.106(d)(2). The commenter stated that, under proposed § 1003.520(c), an aggravating circumstance would exist even if screenings were applied with optimal consistency and fairness. The commenter asserted that even hospitals' and physicians' best efforts to comply with EMTALA will invariably fail to identify an emergency medical condition and, therefore, physicians and hospitals may be subject to maximum CMPs even in cases in which the violation falls short of negligence.

Response: The OIG is finalizing the proposal. While determination of EMTALA violations are fact- and circumstance-dependent, OIG would not impose a CMP where a physician or hospital did not at least demonstrate negligence in failing to comply with EMTALA. Further, if the hospital complied with EMTALA and still failed to diagnose an emergency medical condition, there would be no violation.

Comment: Several commenters addressed OIG's proposed aggravating factors. One commenter expressed concern with including premature discharge in the aggravating factor at § 1003.520(b) given continually evolving triage proposals and Federal guidelines that support reduction in emergency department use. That commenter further stated that all three of OIG's proposed aggravating factors were vague and subject to widely varying

interpretations. Another commenter expressed concern that the use of the phrase ''could have resulted'' in § 1003.520(b) would divorce the list of potential aggravating factors from a causal nexus to the EMTALA violation.

Response: In response to the comments, OIG is revising the proposed aggravating factor at § 1003.520(b) to include only patient harm or risk of patient harm that resulted from the incident. However, ''risk of patient'' harm could, depending on the facts and circumstances of a case, include premature discharge or the need for additional services. The existing regulation requires OIG to prove that patient harm actually resulted from the violation. This formulation is overly constrained. It is highly relevant if the violation put a beneficiary at risk of patient harm. Contrary to the commenter's assertion that the proposed aggravating factors are vague, OIG considers them to be clear and specific and based on OIG's lengthy experience pursuing penalties for violations of EMTALA.

Subpart F—CMPs for Section 1140 Violations

Subpart F applies to violations of section 1140 of the Act (42 U.S.C. 1320b–10). The most significant proposed change to this subpart was clarifying the application of section 1140 of the Act to telemarketing, Internet, and electronic mail solicitations. Section 1140 of the Act, as amended by the Bipartisan Budget Act of 2015 (Bipartisan Budget Act, Pub. L. 114–74, section 814(a), 129 stat. 604 (2015)), prohibits the use of words, letters, symbols, or emblems of HHS, CMS, Medicare, or Medicaid in connection with ''an *advertisement, solicitation,* circular, book, pamphlet, or *other communication (including any Internet or other electronic communication),* or a play, motion picture, broadcast, telecast, or other production'' in a manner that could reasonably be interpreted as conveying the false impression that HHS, CMS, Medicare, or Medicaid has approved, endorsed, or authorized such use. (Emphasis added.)

We previously defined conduct that constituted a violation for (1) direct or printed mailing solicitations or advertisements and (2) broadcasts or telecasts. The proposed regulations were updated to also reflect telephonic and Internet communications. Under a plain reading of the Act, telemarketing solicitations, email, and Web sites fall within the statutory terms emphasized above. In fact, since the publication of the proposed rule, the Bipartisan Budget Act of 2015 amended section 1140(a)(1) of the Act to expressly include Internet and other electronic communications. We believe telephonic and Internet communications are analogous to, and therefore proposed imposing penalties that would apply in the same manner as, those for direct mail and other printed materials. The number of individuals who received direct mail and other printed materials can be more easily quantified than the number of individuals who saw a television commercial or heard a radio commercial. Telemarketing calls, electronic messages, and Web page views can be similarly quantified. Thus, we proposed subjecting telemarketing, email, and Web site violations to the same $5,000 penalty as printed media. Each separate email address that received the email, each telemarketing call, and each Web page view would constitute a separate violation. This proposal is further supported by the Bipartisan Budget Act of 2015, which amended section 1140(b) of the Act to state that, for violations involving the Internet or other electronic communications, ''each dissemination, viewing, or accessing of such communication . . . shall represent a separate violation.'' Bipartisan Budget Act of 2015, section 814(b).

The final rule includes changes from the proposed rule to reflect the Bipartisan Budget Act of 2015. We changed ''electronic message'' and ''electronic mail'' to ''electronic communication.'' We also state ''each dissemination, viewing, or accessing of the electronic communication,'' as opposed to ''each separate email address that received the email message,'' will constitute a violation. The proposed rule used email addresses as a way to determine the number of disseminations, views, or accessing of the communication. Because not all ''electronic communications'' involve an ''email address,'' we believe ''each dissemination, viewing, or accessing of the electronic communication'' is a more appropriate description of potential violations of the rule.

We received no comments on this subpart and finalize, as proposed, except as explained above.

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

Subpart H covers violations for failing to report payments in settlement of a medical malpractice claim in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131); failing to report adverse actions pursuant to section 221 of Public Law 104–191 as set forth in section 1128E of the Act (42 U.S.C. 1320a–7e); or improperly disclosing, using, or permitting access to information reported in accordance with Part B of Title IV of Public Law 99–660 (42 U.S.C. 11137).

The language in proposed subpart H remains largely unchanged from the existing regulations at §§ 1003.102(b)(5)–(6) and §§ 1003.103(c), (g). We proposed to remove the reference to the Healthcare Integrity and Protection Data Bank (HIPDB) in conformity with section 6403(a) of the ACA, which removed the reference from section 1128E of the Act. The relevant reporting requirements, violation, and penalties would remain unchanged. Under section 1128E of the Act, providers must still report the same information. Once the HIPDB is phased out pursuant to section 6403(a) of ACA, the information will be collected and stored in the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 *et seq.*). In the penalty section, we proposed to clarify that a CMP may be imposed for each failure to report required information or adverse action and for each improper disclosure, use, or permitting of access to information.

We received no comments on this subpart and finalize, as proposed.

Subpart I—CMPs for Select Agent Program Violations

Subpart I contains penalties for violations involving select agents, found in the existing regulations at § 1003.102(b)(16) and § 1003.103(l). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002), Public Law 107–188, provides for the regulation of certain biological agents and toxins (referred to below as ''select agents and toxins'') by HHS. The regulations created pursuant to the Bioterrorism Act of 2002 are found at 42 CFR part 73. The regulations set forth requirements for the possession and use in the United States, receipt from outside the United States, and transfer within the United States of the select agents and toxins. For each violation of 42 CFR part 73, OIG is authorized to impose CMPs of up to of $250,000 in the case of an individual, and $500,000 in the case of an entity.

Proposed subpart I explains that the CMP may be assessed for each individual violation of 42 CFR part 73. The Bioterrorism Act of 2002 states that any person who violates ''any provision'' of the regulations is subject to the maximum statutory penalty. The plain meaning of ''any provision'' means that any single violation can

subject a person to the maximum penalty. Thus, we proposed amending the regulation to add ''each individual'' before ''violation'' to clarify our longstanding interpretation of this section to mean that each violation subjects a person to a CMP up to the maximum amount.

In addition, proposed subpart I includes several aggravating circumstances to guide our penalty determinations. Aggravating factors include: (1) The Responsible Official participated in or knew or should have known of the violation; (2) the violation was a contributing factor, regardless of proportionality, to an unauthorized individual's access to or possession of a select agent or toxin, an individual's exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person's physical location as identified on the person's certificate of registration; and (3) the person previously received a statement of deficiency from HHS or the Department of Agriculture for the same or substantially similar conduct. In the final rule, we removed ''regardless of proportionality'' from the second aggravating factor. Such proportionality would be relevant to our qualitative weighing of the aggravating factor, but it would not be relevant to the applicability of the aggravating factor. We also added ''observation'' and ''finding'' to previous ''statements of deficiency'' in the third aggravating factor to better reflect the terminology used by HHS and the Department of Agriculture in Facility Inspection Reports.

We received no comments on this subpart and, except as noted above, finalize, as proposed.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

Subpart J covers two statutory provisions concerning beneficiary inducement violations. We proposed moving the existing regulation, § 1003.102(b)(13), concerning the beneficiary inducement provision in the CMPL (section 1128A(a)(5) of the Act), to this subpart. We also proposed regulatory language for the authority at section 1862(b)(3)(C) of the Act. The statutory authority is self-implementing and does not require a regulation. We proposed adding the regulatory language at this time in light of the general reorganization. Under section 1862(b)(3)(C) of the Act, a penalty of up to $5,000 may be imposed against any person who offers any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act. The proposed regulatory text closely follows the language of the statute.

We proposed to incorporate the general factors listed in § 1003.140 for determining amounts of penalties and assessments for violations in this subpart and to clarify that we will consider the amount of remuneration, other financial incentives, or other incentives. This provision was in the existing regulations at § 1003.106(a)(1)(vii).

We changed the basis for penalties for violations of § 1003.1000(a) in the final rule to reflect the statute, which uses the CMPL default of penalties for each item or service.

We received the following comment on this subpart. As the comment was outside the scope of this rulemaking, we are finalizing this subpart, as proposed, except as explained above.

Comment: A commenter urged OIG to include in proposed § 1003.1000(a) the current exceptions to the beneficiary inducement prohibition. As examples, the commenter included gifts or free services to beneficiaries that do not exceed $10 per item and $50 annually, and services or other remuneration permissibly furnished to financially needy beneficiaries.

Response: Any exceptions to liability under § 1003.1000(a) would be appropriately located in the definition of ''remuneration,'' which is at § 1003.101, not in § 1003.1000(a) itself. Any proposed amendments to the definition of ''remuneration'' are outside the scope of this rulemaking. The OIG proposed changes to that definition in a separate notice of proposed rulemaking, 79 FR 59,717 (October 3, 2014). The OIG plans to address the dollar limits discussed in this comment as part of that other rulemaking. Moreover, the examples raised by the commenter do not clearly fall within any of the exceptions set forth at § 1128A(i)(6) of the Act.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

Subpart K covers violations relating to the sale of Medicare supplemental policies. The statutory authority is self-implementing and does not require a regulation. Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, section 4354(c), 104 Stat. 3327 (1990); 42 U.S.C. 1395ss(d). However, we proposed adding the regulatory language at this time in light of the general reorganization.

The OIG may impose a penalty against any person who it determines has violated section 1882(d)(1) of the Act (42 U.S.C. 1395ss(d)(1)) by knowingly and willfully making or causing to be made or inducing or seeking to induce the making of any false statement or representation of material fact with respect to the compliance of any policy with Medicare supplemental policy standards and requirements or with respect to the use of the Secretary's emblem (described at section 1882(a)(1) of the Act (42 U.S.C. 1395ss(a)(1))) indicating that a policy has received the Secretary's certification. We proposed to add this violation at § 1003.1100(a).

The OIG may impose a penalty against any person who it determines has violated section 1882(d)(2) of the Act (42 U.S.C. 1395ss(d)(2)) by falsely assuming or pretending to be acting, or misrepresenting in any way that he is acting, under the authority of or in association with, Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands or obtains money, paper, documents or anything of value. We proposed to add this violation at § 1003.1100(b).

The OIG may also impose a penalty against any person who it determines has violated section 1882(d)(4)(A) of the Act (42 U.S.C. 1395ss(d)(4)(A)) by mailing or causing to be mailed any matter for advertising, soliciting, offering for sale, or the delivery of Medicare supplemental insurance policy that has not been approved by the State commissioner or superintendent of insurance. We proposed to add this violation at § 1003.1100(c).

The OIG may impose a penalty against any person who it determines has violated section 1882(d)(3)(A)(i) of the Act (42 U.S.C. 1395ss(d)(3)(A)) by issuing or selling to an individual entitled to benefits under Part A or enrolled in Part B (including an individual electing a Medicare Part C plan): (1) A health insurance policy with the knowledge that the policy duplicates Medicare or Medicaid health benefits to which the individual is otherwise entitled; (2) a Medicare supplemental policy to an individual who has not elected a Medicare Part C plan where the person knows that the individual is entitled to benefits under another Medicare supplemental policy; (3) a Medicare supplemental policy to an individual who has elected a Medicare Part C plan where the person knows that the policy duplicates health

benefits to which the individual is otherwise entitled under the Medicare Part C plan or under another Medicare supplemental policy; and (4) a health insurance policy (other than a Medicare supplemental policy) with the knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law. We proposed to add this violation at § 1003.1100(d).

The OIG may also impose a penalty against any person who violated section 1882(d)(3)(A)(vi)(II) of the Act (42 U.S.C. 1395ss(d)(3)(A)(vi)(II)) by issuing or selling a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III) of the Act) to an individual entitled to benefits under Part A or enrolled under Part B who is applying for a health insurance policy without furnishing a disclosure statement (described at section 1882(d)(3)(A)(vii) of the Act). We proposed to add this violation at § 1003.1100(e).

The OIG may also impose a penalty against any person who it determines has violated section 1882(d)(3)(B)(iv) of the Act (42 U.S.C. 1395ss(d)(3)(B)(iv)) by issuing or selling a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Part B without obtaining the written statement from the individual or written acknowledgement from the seller required by section 1882(d)(3)(B) of the Act (42 U.S.C. 1395ss(d)(3)(B)). We proposed to add this violation at § 1003.1100(f).

For violations of section 1882(d)(1), (d)(2), and (d)(4)(A) of the Act, OIG may impose a penalty of not more than $5,000 for each violation. We proposed to add this penalty at § 1003.1110(a). For violations of section 1882(d)(3)(A) and (B) of the Act, OIG may impose a penalty of not more than $25,000 for each violation by a seller that is also the issuer of the policy and a penalty of not more than $15,000 for each violation by a seller that is not the issuer of the policy. We proposed to add these penalties at §§ 1003.1110(b) and (c). In determining the amount of the penalty in accordance with proposed subpart K, OIG would consider the factors listed in the proposed § 1003.140.

We received the following comment on this subpart. As discussed below, we are finalizing this subpart, as proposed.

Comment: A commenter requested that OIG defer adopting the proposed § 1003.1100(d), which relates to the issuance or sale of duplicative coverage, until the application of the prohibitions in that section to QHPs and State and Federally facilitated exchanges are better understood. The commenter stated that questions arose during the 2013 open enrollment period for exchange-based health insurance coverage as to individuals eligible for or enrolled in Medicare and exchange-based health insurance coverage. According to the commenter, some exchanges did not inquire as to a beneficiary's Medicare status prior to instructing plans to enroll these individuals into QHPs. The commenter asserted that exchanges are best-positioned to verify an individual's Medicare status and that it would be inappropriate to penalize QHPs under this CMP authority.

Response: We respectfully disagree with the suggestion to defer issuance of the regulation and are finalizing the rule, as proposed. The CMP authorities covered in this subpart have existed in statute for many years and should be added to part 1003 at this time in light of our reorganization. In addition, the concerns raised by the commenter appear to be addressed by the fact that § 1003.1100(d)(1) and (2) apply only when a health insurance policy is issued with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled.

Subpart L—CMPs for Drug Price Reporting

Subpart L contains the CMPs for drug-price reporting found in section 1927(b)(3)(B)–(C) of the Act (42 U.S.C. 1396r–8(b)(3)(B)–(C)). Although the statutory authority is self-implementing and does not require a regulation, we proposed adding the regulatory language at this time in light of the general reorganization. The proposed regulation text closely mirrors the language of the statute.

Section 1927(a) of the Act implements a drug-pricing program in which manufacturers that sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. Under section 1927(a) of the Act, manufacturers must provide certain statutorily mandated discounts to covered entities. Section 1927(b)(3)(A) of the Act requires manufacturers with Medicaid Drug Rebate Agreements to provide specified drug-pricing and product information to the Secretary, including, but not limited to, average manufacturer price (AMP), average sales price (ASP), wholesale acquisition cost, and best price. Labelers are required to certify each product and pricing data submission made to CMS.

Manufacturers submit the product and pricing information required by section 1927 of the Act using the National Drug Code (NDC) product identifier. The OIG proposed calculating CMPs under section 1927(b)(3)(C) of the Act at the NDC level. For example, a manufacturer that fails to provide the information required by section 1927(b)(3)(A) of the Act for five separate NDCs may be penalized for each NDC, in an aggregate amount of not more than $50,000 per day for each day that the information is not provided. If, after 2 days, the manufacturer in this example submitted information for two of the missing NDCs, the manufacturer would be subject to an aggregate penalty of not more than $30,000 per day for each additional day that information was not provided for the remaining three NDCs. The OIG believes that this interpretation is supported by the statutory text, which refers to NDCs, and by the reporting systems employed by CMS, under which manufacturers are required to report AMP and ASP product and pricing data using NDCs.

Section 1927(b)(3)(B) of the Act provides for verification surveys of AMPs and establishes that a penalty of not more than $100,000 may be imposed against a wholesaler, direct seller, or manufacturer that directly distributes its covered outpatient drugs for refusing a request for information by, or for knowingly providing false information to, the Secretary about charges or prices in connection with such a survey.

Pursuant to section 1927(b)(3)(C) of the Act, OIG may impose a penalty of not more than $100,000 against any manufacturer with an agreement under section 1927 of the Act that knowingly provides false information for each item of false information.

We received the following comments on this subpart. To the extent provisions of the proposed rule are not addressed in our response to the comments below, we are finalizing this section of the rule, as proposed.

Comment: One commenter expressed concern with OIG's proposal to calculate penalties at the NDC level instead of per late report. The commenter argued that, where one report contained multiple NDCs, imposing multiple penalties per day instead of one penalty per day would be unduly harsh.

Response: The OIG is finalizing the rule, as proposed. The OIG believes that this interpretation is supported by the statutory text, which refers to NDCs, and by the reporting systems employed by CMS, under which manufacturers are required to report AMP and ASP product and pricing data using NDCs.

Comment: One commenter expressed concern with OIG's proposal to

calculate penalties at the 9-digit NDC level. The commenter suggested that OIG avoid establishment of a bright-line rule that would rigidly define products at the 9-digit NDC level for the purposes of calculating penalties. This commenter noted that the preamble language in which OIG proposed calculating penalties at the 9-digit NDC level is not reflected in the regulation text.

Response: We agree that OIG should have discretion to determine the appropriate NDC level at which to calculate penalties based on the particular requirements and submissions for each manufacturer. Neither section 1927(b)(3)(C) of the Act nor the regulation dictates which NDC level must be used in calculating the penalties. Therefore, we have not included the discussion of 9-digit and 11-digit NDC levels in the text of the final rule. To the extent the commenter may have been recommending that OIG not use NDCs to calculate penalties, OIG believes that the use of NDCs is appropriate based on the statutory text and the reporting systems employed by CMS.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

In subpart M, we proposed to add regulations providing for CMPs for notifying a skilled nursing facility (SNF), nursing facility (NF), home health agency (HHA), or a community care setting of the date or time of a survey. The statutory authority for these CMPs is self-implementing and does not require a regulation. Sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), 1929(i)(3)(A); 42 U.S.C. 1395i–3(g)(2)(A), 1396r(g)(2)(A), 1395bbb(c)(1), 1396t(i)(3)(A) of the Act. However, we proposed adding the regulatory language at this time in light of the general reorganization. The proposed regulation text closely mirrors the language of the statute.

SNFs, NFs, HHAs, and community care settings are subject to State compliance surveys without any prior notice. Sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), and 1929(i)(3)(A) of the Act provide for imposing a penalty of not more than $2,000 against any individual who notifies, or causes to be notified, a SNF, NF, home health agency, or community care setting of the time or date on which a survey is scheduled to be conducted.

The OIG will consider the general factors listed in § 1003.140 when determining the amount of the penalties to be imposed under this subpart.

We received no comments on this subpart and finalize, as proposed.

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

Subpart O contains the procedural provisions that apply to part 1003. We proposed several clarifying changes to procedures in this subpart. We proposed amending the methods permitted for service of a notice of a proposal of a penalty, assessment, or exclusion under part 1003. Section 1003.109 required service by certified mail, return receipt requested. Section 1128A(c)(1) of the Act, however, permits service by any method authorized by Rule 4 of the Federal Rules of Civil Procedure (FRCP), which has been amended to authorize various service methods depending on whether the recipient is a domestic or foreign individual or corporation. Therefore, we are amending our regulation at §§ 1003.1500(a) and 1003.1510 to permit service under any means authorized by FRCP Rule 4. By referencing the rule, the regulation would reflect any future amendments to Rule 4 automatically.

We also proposed technical changes to the judicial review provision at § 1003.127 in the existing regulation and redesignated as § 1003.1540 to better conform to the statutory scheme requiring a person to exhaust his or her administrative remedies before filing a claim in Federal court. Exhaustion of administrative remedies is a well-settled legal principle, particularly concerning section 405(g) of the Act (42 U.S.C. 205(g)). Consistent with existing law, the proposed regulations clarify that a person may not bring a claim in Federal court without first raising that claim at every applicable stage within the administrative process, including any administrative appeal process. In the context of part 1003, that administrative process consists of making a timely request for a hearing before an ALJ pursuant to 42 CFR 1005.2 and, if the respondent loses at the ALJ level, timely filing an appeal of the ALJ decision to the Appellate Division of the Departmental Appeals Board. Only after the Departmental Appeals Board makes a final decision under 42 CFR 1005.21(j) is the respondent eligible to file an action in Federal court.

We also proposed a technical change to the regulatory language to clarify the statutory limit on issues eligible for judicial review. Section 1128A(e) of the Act provides that ''[n]o objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances.'' We interpret this to mean that a person is precluded from making arguments or raising issues in Federal court that were not first raised during the administrative process, unless the court finds that extraordinary circumstances prevented raising those arguments or issues. We interpret ''extraordinary circumstances'' to mean that those arguments or issues were beyond the authority of the administrative process.

We received no comments on this subpart and finalize, as proposed.

Other Changes in Part 1003

The OIG has authority to impose CMPs against endorsed sponsors under the Medicare Prescription Drug Discount Card Program that knowingly commit certain violations. The discount card program has been defunct since January 1, 2006, when Medicare Part D went into effect. We proposed to remove this CMP from the regulations as the statute of limitations has expired for any conduct that might implicate this CMP.

We received no comments on removing this CMP and finalize, as proposed.

F. Appeals of Exclusions, Civil Monetary Penalties, and Assessments

We proposed changes to OIG regulations at 42 CFR part 1005 to correct an internal inconsistency in § 1005.4(c). The regulation states at § 1005.4(c)(5)–(6) that an ALJ is not authorized to (1) review the exercise of discretion by OIG to exclude an individual or entity under section 1128(b) of the Act, (2) determine the scope or effect of the exclusion, or (3) set a period of exclusion at zero when the ALJ finds that the individual or entity committed an act described in section 1128(b) of the Act. Section 1005.4(c)(7) stated that an ALJ is not authorized to review the exercise of discretion by OIG to impose a CMP, an assessment, or an exclusion under part 1003. The second and third limits on ALJ authority with respect to exclusions under section 1128(b) of the Act should also apply to exclusions imposed under part 1003. To correct this inconsistency, we proposed to clarify that when reviewing exclusions imposed pursuant to part 1003, an ALJ is not authorized to (1) review OIG's exercise of discretion to exclude an individual or entity, (2) determine the scope or effect of the exclusion, or (3) set a period of exclusion at zero if the ALJ finds that the individual or entity committed an act described in part 1003. We believe that this requirement is consistent with congressional intent in enacting the statutes providing authority for part

1003 that explicitly provide for exclusion as an appropriate remedy for the commission of any of the acts specified in those statutes. Thus, in every case in which OIG has exercised its discretion to impose an exclusion and when the ALJ decides that a violation did occur, exclusion is appropriate.

We received the following comment on this proposal. As discussed in response to the comment, we are finalizing this section of the rule, as proposed.

Comment: A commenter asked OIG to reconsider our proposal to limit an ALJ's authority in the absence of a specific legislative mandate.

Response: We respectfully disagree with the commenter's suggestion and finalize the rule, as proposed. The rule ensures consistency in the ALJ review of discretionary exclusions imposed under sections 1128(b) and 1128A of the Act.

III. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

Executive Order Nos. 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. A regulatory impact analysis must be prepared for major rules with economically significant effects, *i.e.,* $100 million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold.

This proposed rule is designed to codify in regulations new statutory provisions, including new CMP authorities. This proposed rule is also designed to clarify the intent of existing statutory requirements and to reorganize CMP regulation sections for ease of use. The vast majority of providers, suppliers, and other persons participating in Federal health care programs would be minimally affected, if at all, by these proposed revisions.

Accordingly, we believe that the likely aggregate economic effect of these regulations would be significantly less than $100 million.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered small entities if they have revenues of $5 million to $25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The aggregate effect of the changes to the CMP provisions would be minimal.

In summary, we have concluded that this proposed rule should not have a significant impact on the operations of a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking.

In addition, section 1102(b) of the Act (42 U.S.C. 1302) requires us to prepare a regulatory impact analysis if a rule under Titles XVIII or XIX or section B of Title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to section 604 of the RFA. Only one proposed change has been made under the relevant title, the amendments to the Medicare Contracting Organization Rule at proposed § 1003.400, *et seq.* This rule applies only to Medicare contracting organizations, not to rural hospitals, and would have no effect on rural hospitals. Thus, an analysis under section 1102(b) is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million or more. As indicated above, these proposed revisions comport with statutory amendments and clarify existing law. We believe that as a result, there would be no significant costs associated with these proposed revisions that would impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of $110 million or more (adjusted for inflation) in any given year and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

IV. Paperwork Reduction Act

These proposed changes to parts 1003 and 1005 impose no new reporting requirements or collections of information. Therefore, a Paperwork Reduction Act review is not required.

List of Subjects

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

42 CFR Part 1005

Administrative practice and procedure, Fraud, Investigations, Penalties.

For the reasons set forth in the preamble, the Office of the Inspector General, Department of Health and Human Services, amends 42 CFR chapter V, subchapter B as follows:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 2. Designate §§ 1003.100 through 1003.135 as subpart A, and add a heading for subpart A to read as follows:

Subpart A—General Provisions

■ 3. Revise § 1003.100 to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1819(b)(3)(B), 1819(g)(2)(A), 1857(g)(2)(A), 1860D–12(b)(3)(E), 1860D–31(i)(3), 1862(b)(3)(C), 1867(d)(1), 1876(i)(6), 1877(g), 1882(d),

1891(c)(1); 1903(m)(5), 1919(b)(3)(B), 1919(g)(2)(A), 1927(b)(3)(B), 1927(b)(3)(C), and 1929(i)(3) of the Social Security Act; sections 421(c) and 427(b)(2) of Public Law 99–660; and section 201(i) of Public Law 107–188 (42 U.S.C. 1320a–7(c), 1320a–7a, 1320b–10, 1395i–3(b)(3)(B), 1395i–3(g)(2)(A), 1395w–27(g)(2)(A), 1395w–112(b)(3)(E), 1395w–141(i)(3), 1395y(b)(3)(B), 1395dd(d)(1), 1395mm(i)(6), 1395nn(g), 1395ss(d), 1395bbb(c)(1), 1396b(m)(5), 1396r(b)(3)(B), 1396r(g)(2)(A), 1396r–8(b)(3)(B), 1396r–8(b)(3)(C), 1396t(i)(3), 11131(c), 11137(b)(2), and 262a(i)).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments and exclusions against persons who have committed an act or omission that violates one or more provisions of this part and

(2) Sets forth the appeal rights of persons subject to a penalty, assessment, and exclusion.

§§ 1003.102 through 1003.110, 1003.114, 1003.126 through 1003.129, and 1003.132 through 1003.135 [Removed]

■ 4. Remove §§ 1003.102 through 1003.110, 1003.114, 1003.126 through 1003.129, and 1003.132 through 1003.135.

§ 1003.101 [Redesignated as § 1003.110]

■ 5. Redesignate § 1003.101 as § 1003.110.

■ 6. Amend newly designated § 1003.110 by:

■ a. Removing the definitions of ''Act'', ''Adverse effect'', and ''ALJ'';

■ b. Revising the definitions of ''Assessment'' and ''Claim'';

■ c. Removing the definition of ''CMS'';

■ d. Revising the definitions of ''Contracting organization'' and ''Enrollee'';

■ e. Removing the definitions of ''Department'', ''Exclusion'', ''Inspector General'', and ''Item or service'';

■ f. Adding in alphabetical order definitions for ''Items and services or items or services'', ''Knowingly'', and ''Material'';

■ g. Removing the definition of ''Medicaid'';

■ h. Revising the definition of ''Medical malpractice claim or action'';

■ i. Removing the definition of ''Medicare'';

■ j. Adding in alphabetical order definitions for ''Non-separately-billable item or service'', and ''Overpayment'';

■ k. Revising the definitions of ''Participating hospital'', ''Penalty'', and ''Physician incentive plan'';

■ l. Adding in alphabetical order definitions for ''Reasonable request'', and ''Responsible Official'';

■ m. Revising the definition of ''Responsible physician'';

■ n. Removing the definition of ''Secretary'';

■ o. Revising the definition of ''Select agents and toxins'';

■ p. Adding in alphabetical order a definition for ''Separately billable item or service'';

■ q. Revising the definitions of ''Should know, or should have known'' and ''Social Services Block Grant Program'';

■ r. Removing the definitions of ''State'' and ''State health care program'';

■ s. Revising the definition of ''Timely basis''; and

■ t. Removing the definition of ''Transitional assistance''.

The revisions and additions read as follows:

§ 1003.110 Definitions.

* * * * *

Assessment means the amounts described in this part and includes the plural of that term.

Claim means an application for payment for an item or service under a Federal health care program.

* * * * *

Contracting organization means a public or private entity, including a health maintenance organization, Medicare Advantage organization, Prescription Drug Plan sponsor, or other organization that has contracted with the Department or a State to furnish, or otherwise pay for, items and services to Medicare or Medicaid beneficiaries pursuant to sections 1857, 1860D–12, 1876(b), or 1903(m) of the Act.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization.

* * * * *

Items and services or items or services includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative services), including, but not limited to, those that are listed in an itemized claim for program payment or a request for payment; for which payment is included in any Federal or State health care program reimbursement method, such as a prospective payment system or managed care system; or that are, in the case of a claim based on costs, required to be entered in a cost report, books of account, or other documents supporting the claim (whether or not actually entered).

Knowingly means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.

Material means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

* * * * *

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's, or other health care practitioner's provision of, or failure to provide, health care services and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

* * * * *

Non-separately-billable item or service means an item or service that is a component of, or otherwise contributes to the provision of, an item or a service, but is not itself a separately billable item or service.

Overpayment means any funds that a person receives or retains under Medicare or Medicaid to which the person, after applicable reconciliation, is not entitled under such program.

Participating hospital means either a hospital or a critical access hospital, as defined in section 1861(mm)(1) of the Act, that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in this part and includes the plural of that term.

* * * * *

Physician incentive plan means any compensation arrangement between a contracting organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

* * * * *

Reasonable request, with respect to § 1003.200(b)(10), means a written request, signed by a designated representative of the OIG and made by a properly identified agent of the OIG during reasonable business hours. The request will include: A statement of the authority for the request, the person's rights in responding to the request, the definition of ''reasonable request'' and ''failure to grant timely access'' under part 1003, the deadline by which the OIG requests access, and the amount of the civil money penalty or assessment that could be imposed and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and

the earliest date that a request for reinstatement would be considered.

* * * * *

Responsible Official means the individual designated pursuant to 42 CFR part 73 to serve as the Responsible Official for the person holding a certificate of registration to possess, use, or transfer select agents or toxins.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department requesting examination or treatment, including any physician who is on-call for the care of such individual and fails or refuses to appear within a reasonable time at such hospital to provide services relating to the examination, treatment, or transfer of such individual. *Responsible physician* also includes a physician who is responsible for the examination or treatment of individuals at hospitals with specialized capabilities or facilities, as provided under section 1867(g) of the Act, including any physician who is on-call for the care of such individuals and refuses to accept an appropriate transfer or fails or refuses to appear within a reasonable time to provide services related to the examination or treatment of such individuals.

* * * * *

Select agents and toxins is defined consistent with the definition of ''select agent and/or toxin'' and ''overlap select agent and/or toxin'' as set forth in 42 CFR part 73.

Separately billable item or service means an item or service for which an identifiable payment may be made under a Federal health care program, *e.g.,* an itemized claim or a payment under a prospective payment system or other reimbursement methodology.

Should know, or should have known, means that a person, with respect to information, either acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant Program means the program authorized under Title XX of the Act.

* * * * *

Timely basis means, in accordance with § 1003.300(a) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

* * * * *

■ 7. Add §§ 1003.120, 1003.130, 1003.140, 1003.150, and 1003.160 to subpart A to read as follows:

Sec.

* * * * *

1003.120 Liability for penalties and assessments.
1003.130 Assessments.
1003.140 Determinations regarding the amount of penalties and assessments and the period of exclusion.
1003.150 Delegation of authority.
1003.160 Waiver of exclusion.

§ 1003.120 Liability for penalties and assessments.

(a) In any case in which it is determined that more than one person was responsible for a violation described in this part, each such person may be held liable for the penalty prescribed by this part.

(b) In any case in which it is determined that more than one person was responsible for a violation described in this part, an assessment may be imposed, when authorized, against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(c) Under this part, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of his or her agency. This provision does not limit the underlying liability of the agent.

§ 1003.130 Assessments.

The assessment in this part is in lieu of damages sustained by the Department or a State agency because of the violation.

§ 1003.140 Determinations regarding the amount of penalties and assessments and the period of exclusion.

(a) Except as otherwise provided in this part, in determining the amount of any penalty or assessment or the period of exclusion in accordance with this part, the OIG will consider the following factors—

(1) The nature and circumstances of the violation;

(2) The degree of culpability of the person against whom a civil money penalty, assessment, or exclusion is proposed. It should be considered an aggravating circumstance if the respondent had actual knowledge where a lower level of knowledge was required to establish liability (*e.g.,* for a provision that establishes liability if the respondent ''knew or should have known'' a claim was false or fraudulent, it will be an aggravating circumstance if the respondent knew the claim was false or fraudulent). It should be a mitigating circumstance if the person took appropriate and timely corrective action in response to the violation. For purposes of this part, corrective action must include disclosing the violation to the OIG through the Self-Disclosure Protocol and fully cooperating with the OIG's review and resolution of such disclosure, or in cases of physician self-referral law violations, disclosing the violation to CMS through the Self-Referral Disclosure Protocol;

(3) The history of prior offenses. Aggravating circumstances include, if at any time prior to the violation, the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or in connection with the delivery of a health care item or service;

(4) Other wrongful conduct. Aggravating circumstances include proof that the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to a government program or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance; and

(5) Such other matters as justice may require. Other circumstances of an aggravating or mitigating nature should be considered if, in the interests of justice, they require either a reduction or an increase in the penalty, assessment, or period of exclusion to achieve the purposes of this part.

(b)(1) After determining the amount of any penalty and assessment in accordance with this part, the OIG considers the ability of the person to pay the proposed civil money penalty or assessment. The person shall provide, in a time and manner requested by the OIG, sufficient financial documentation,

including, but not limited to, audited financial statements, tax returns, and financial disclosure statements, deemed necessary by the OIG to determine the person's ability to pay the penalty or assessment.

(2) If the person requests a hearing in accordance with 42 CFR 1005.2, the only financial documentation subject to review is that which the person provided to the OIG during the administrative process, unless the ALJ finds that extraordinary circumstances prevented the person from providing the financial documentation to the OIG in the time and manner requested by the OIG prior to the hearing request.

(c) In determining the amount of any penalty and assessment to be imposed under this part the following circumstances are also to be considered—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by this part to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by this part to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should not be less than double the approximate amount of damages and costs (as defined by paragraph (e)(2) of this section) sustained by the United States, or any State, as a result of the violation.

(4) The presence of any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors is present.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including, but not limited to, the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this part limits the authority of the Department or the OIG to settle any issue or case as provided by § 1003.1530 or to compromise any exclusion and any penalty and assessment as provided by § 1003.1550.

(4) Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties, assessments, or other sanctions prescribed by law.

§ 1003.150 Delegation of authority.

The OIG is delegated authority from the Secretary to impose civil money penalties and, as applicable, assessments and exclusions against any person who has violated one or more provisions of this part. The delegation of authority includes all powers to impose and compromise civil monetary penalties, assessments, and exclusion under section 1128A of the Act.

§ 1003.160 Waiver of exclusion.

(a) The OIG will consider a request from the administrator of a Federal health care program for a waiver of an exclusion imposed under this part as set forth in paragraph (b) of this section. The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) If the OIG subsequently obtains information that the basis for a waiver no longer exists, the waiver will cease and the person will be fully excluded from the Federal health care programs for the remainder of the exclusion period, measured from the time the full exclusion would have been imposed if the waiver had not been granted.

(c) The OIG will notify the administrator of the Federal health care program whether his or her request for a waiver has been granted or denied.

(d) If a waiver is granted, it applies only to the program(s) for which waiver is requested.

(e) The decision to grant, deny, or rescind a waiver is not subject to administrative or judicial review.

■ 8. Add subparts B through F to read as follows:

Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

Sec.
1003.200 Basis for civil money penalties, assessments, and exclusions.
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Subpart B—CMPs, Assessments, and Exclusions for False or Fraudulent Claims and Other Similar Misconduct

§ 1003.200 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, assessment, and an exclusion against any person who it determines has knowingly presented, or caused to be presented, a claim that was for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that was part of a pattern or practice of claims based on codes that the person knew, or should have known, would result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was presented;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified by a medical specialty board when he or she was not so certified; or

(5) An item or service that a person knew, or should have known was not

medically necessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty; an exclusion; and, where authorized, an assessment against any person who it determines—

(1) Has knowingly presented, or caused to be presented, a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1) of the Act; or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act;

(2) Has knowingly given, or caused to be given, to any person, in the case of inpatient hospital services subject to section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital;

(3) Is an individual who is excluded from participating in a Federal health care program under section 1128 or 1128A of the Act, and who—

(i) Knows, or should know, of the action constituting the basis for the exclusion and retains a direct or indirect ownership or control interest of 5 percent or more in an entity that participates in a Federal health care program or

(ii) Is an officer or a managing employee (as defined in section 1126(b) of the Act) of such entity;

(4) Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program;

(5) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under a Federal health care program if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act or violates the requirements for such an arrangement;

(6) Orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program, in the case when the person knows, or should know, that a claim for such medical or other item or service will be made under such a program;

(7) Knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program, including contracting organizations, and entities that apply to participate as providers of services or suppliers in such contracting organizations;

(8) Knows of an overpayment and does not report and return the overpayment in accordance with section 1128J(d) of the Act;

(9) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(10) Fails to grant timely access to records, documents, and other material or data in any medium (including electronically stored information and any tangible thing), upon reasonable request, to the OIG, for the purpose of audits, investigations, evaluations, or other OIG statutory functions. Such failure to grant timely access means:

(i) Except when the OIG reasonably believes that the requested material is about to be altered or destroyed, the failure to produce or make available for inspection and copying the requested material upon reasonable request or to provide a compelling reason why they cannot be produced, by the deadline specified in the OIG's written request, and

(ii) When the OIG has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

(c) The OIG may impose a penalty against any person who it determines, in accordance with this part, is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements in section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(d) The OIG may impose a penalty against any person who it determines knowingly certifies, or causes another individual to certify, a material and false statement in a resident assessment pursuant to sections 1819(b)(3)(B) and 1919(b)(3)(B).

§ 1003.210 Amount of penalties and assessments.

(a) *Penalties.*[1] (1) Except as provided in this section, the OIG may impose a penalty of not more than $10,000 for each individual violation that is subject to a determination under this subpart.

(2) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under § 1003.200(b)(2).

(3) The OIG may impose a penalty of not more than $10,000 per day for each day that the prohibited relationship described in § 1003.200(b)(3) occurs.

(4) For each individual violation of § 1003.200(b)(4), the OIG may impose a penalty of not more than $10,000 for each separately billable or non-separately-billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity.

(5) The OIG may impose a penalty of not more than $2,000 for each bill or request for payment for items and services furnished to a hospital patient in violation of § 1003.200(b)(5).

(6) The OIG may impose a penalty of not more than $50,000 for each false statement, omission, or misrepresentation of a material fact in violation of § 1003.200(b)(7).

(7) The OIG may impose a penalty of not more than $50,000 for each false record or statement in violation of § 1003.200(b)(9).

(8) The OIG may impose a penalty of not more than $10,000 for each item or service related to an overpayment that is not reported and returned in accordance with section 1128J(d) of the Act in violation of § 1003.200(b)(8).

(9) The OIG may impose a penalty of not more than $15,000 for each day of failure to grant timely access in violation of § 1003.200(b)(10).

(10) For each false certification in violation of § 1003.200(c), the OIG may impose a penalty of not more than the greater of—

(i) $5,000; or

(ii) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a

[1] The penalty amounts in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

physician, as prohibited by section 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(11) For each false certification in violation of § 1003.200(d), the OIG may impose a penalty of not more than—

(i) $1,000 with respect to an individual who willfully and knowingly falsely certifies a material and false statement in a resident assessment; and

(ii) $5,000 with respect to an individual who willfully and knowingly causes another individual to falsely certify a material and false statement in a resident assessment.

(b) *Assessments.* (1) Except for violations of § 1003.200(b)(4), (5), and (7), and § 1003.200(c) and (d), the OIG may impose an assessment for each individual violation of § 1003.200, of not more than 3 times the amount claimed for each item or service.

(2) For violations of § 1003.200(b)(4), the OIG may impose an assessment of not more than 3 times—

(i) The amount claimed for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity or

(ii) The total costs (including salary, benefits, taxes, and other money or items of value) related to the excluded individual or entity incurred by the person that employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(3) For violations of § 1003.200(b)(7), the OIG may impose an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement, omission, or misrepresentation of material fact.

§ 1003.220 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140—

(a) It should be considered a mitigating circumstance if all the items or services or violations included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or violations, and the total amount claimed or requested for such items or services was less than $5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items or services or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services, or the amount of the overpayment was $50,000 or more;

(4) The violation resulted, or could have resulted, in patient harm, premature discharge, or a need for additional services or subsequent hospital admission; or

(5) The amount or type of financial, ownership, or control interest or the degree of responsibility a person has in an entity was substantial with respect to an action brought under § 1003.200(b)(3).

Subpart C—CMPs, Assessments, and Exclusions for Anti-Kickback and Physician Self-Referral Violations

§ 1003.300 Basis for civil money penalties, assessments, and exclusions.

The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines in accordance with this part—

(a) Has not refunded on a timely basis, as defined in § 1003.110, amounts collected as a result of billing an individual, third party payer, or other entity for a designated health service furnished pursuant to a prohibited referral as described in 42 CFR 411.353.

(b) Is a physician or other person who enters into any arrangement or scheme (such as a cross-referral arrangement) that the physician or other person knows, or should know, has a principal purpose of ensuring referrals by the physician to a particular person that, if the physician directly made referrals to such person, would be in violation of the prohibitions of 42 CFR 411.353.

(c) Has knowingly presented, or caused to be presented, a claim that is for a payment that such person knows, or should know, may not be made under 42 CFR 411.353;

(d) Has violated section 1128B(b) of the Act by unlawfully offering, paying, soliciting, or receiving remuneration to induce or in return for the referral of business paid for, in whole or in part, by Medicare, Medicaid, or other Federal health care programs.

§ 1003.310 Amount of penalties and assessments.

(a) *Penalties.*[2] The OIG may impose a penalty of not more than—

(1) $15,000 for each claim or bill for a designated health service, as defined in § 411.351 of this title, that is subject to a determination under § 1003.300(a) or (c);

(2) $100,000 for each arrangement or scheme that is subject to a determination under § 1003.300(b); and

(3) $50,000 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under § 1003.300(d).

(b) *Assessments.* The OIG may impose an assessment of not more than 3 times—

(1) The amount claimed for each designated health service that is subject to a determination under § 1003.300(a), (b), or (c).

(2) The total remuneration offered, paid, solicited, or received that is subject to a determination under § 1003.300(d). Calculation of the total remuneration for purposes of an assessment shall be without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose.

§ 1003.320 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In considering the factors listed in § 1003.140:

(a) It should be considered a mitigating circumstance if all the items, services, or violations included in the action brought under this part were of the same type and occurred within a short period of time; there were few such items, services, or violations; and the total amount claimed or requested for such items or services was less than $5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items, services, or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services or the amount of the remuneration was $50,000 or more; or

(4) The violation resulted, or could have resulted, in harm to the patient, a premature discharge, or a need for additional services or subsequent hospital admission.

[2] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

§ 1003.400 Basis for civil money penalties and assessments.

(a) *All contracting organizations.* The OIG may impose a penalty against any contracting organization that—

(1) Fails substantially to provide an enrollee with medically necessary items and services that are required (under the Act, applicable regulations, or contract with the Department or a State) to be provided to such enrollee and the failure adversely affects (or has the substantial likelihood of adversely affecting) the enrollee;

(2) Imposes a premium on an enrollee in excess of the amounts permitted under the Act;

(3) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by beneficiaries whose medical condition or history indicates a need for substantial future medical services, except as permitted by the Act;

(4) Misrepresents or falsifies information furnished to a person under sections 1857, 1860D–12, 1876, or 1903(m) of the Act;

(5) Misrepresents or falsifies information furnished to the Secretary or a State, as applicable, under sections 1857, 1860D–12, 1876, or 1903(m) of the Act;

(6) Fails to comply with the requirements of 42 CFR 417.479(d) through (i) for Medicare and 42 CFR 417.479(d) through (g) and (i) for Medicaid regarding certain prohibited incentive payments to physicians; or

(7) Fails to comply with applicable requirements of the Act regarding prompt payment of claims.

(b) *All Medicare contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1857, 1860D–12, or 1876 of the Act that—

(1) Acts to expel or to refuse to reenroll a beneficiary in violation of the Act; or

(2) Employs or contracts with a person excluded, under section 1128 or 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services, or employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded person.

(c) *Medicare Advantage and Part D contracting organizations.* The OIG may impose a penalty, and for § 1003.400(c)(4) or (5), an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act that:

(1) Enrolls an individual without the individual's (or his or her designee's) prior consent, except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1) of the Act;

(2) Transfers an enrollee from one plan to another without the individual's (or his or her designee's) prior consent;

(3) Transfers an enrollee solely for the purpose of earning a commission;

(4) Fails to comply with marketing restrictions described in subsection (h) or (j) of section 1851 of the Act or applicable implementing regulations or guidance; or

(5) Employs or contracts with any person who engages in the conduct described in paragraphs (a) through (c) of this section.

(d) *Medicare Advantage contracting organizations.* The OIG may impose a penalty against a contracting organization with a contract under section 1857 of the Act that fails to comply with the requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii) of the Act.

(e) *Medicaid contracting organizations.* The OIG may impose a penalty against any contracting organization with a contract under section 1903(m) of the Act that acts to discriminate among individuals in violation of the Act, including expulsion or refusal to reenroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals with the contracting organization whose medical condition or history indicates a need for substantial future medical services.

§ 1003.410 Amount of penalties and assessments for Contracting Organization.

(a) *Penalties.*[3] (1) The OIG may impose a penalty of up to $25,000 for each individual violation under § 1001.400, except as provided in this section.

(2) The OIG may impose a penalty of up to $100,000 for each individual violation under § 1003.400(a)(3), (a)(5), or (e).

(b) *Additional penalties.* In addition to the penalties described in paragraph (a) of this section, the OIG may impose—

(1) An additional penalty equal to double the amount of excess premium charged by the contracting organization for each individual violation of § 1003.400(a)(2). The excess premium amount will be deducted from the penalty and returned to the enrollee.

(2) An additional $15,000[4] penalty for each individual expelled or not enrolled in violation of § 1003.400(a)(3) or (e).

(c) *Assessments.* The OIG may impose an assessment against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) of not more than the amount claimed in violation of § 1003.400(a)(4) or (a)(5) on the basis of the misrepresentation or falsified information involved.

(d) The OIG may impose a penalty or, when applicable, an assessment, against a contracting organization with a contract under section 1857 or 1860D–12 of the Act (Medicare Advantage or Part D) if any of its employees, agents, or contracting providers or suppliers engages in any of the conduct described in § 1003.400(a) through (d).

§ 1003.420 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in § 1003.140, aggravating circumstances include—

(a) Such violations were of several types or occurred over a lengthy period of time;

(b) There were many such violations (or the nature and circumstances indicate a pattern of incidents);

(c) The amount of money, remuneration, damages, or tainted claims involved in the violation was $15,000 or more; or

(d) Patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; and

(e) The contracting organization knowingly or routinely engaged in any prohibited practice that acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization.

Subpart E—CMPs and Exclusions for EMTALA Violations

§ 1003.500 Basis for civil money penalties and exclusions.

(a) The OIG may impose a penalty against any participating hospital with an emergency department or specialized capabilities or facilities for each negligent violation of section 1867 of the Act or § 489.24 (other than § 489.24(j)) of this title.

[3] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[4] This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(b) The OIG may impose a penalty against any responsible physician for each—

(1) Negligent violation of section 1867 of the Act;

(2) Certification signed under section 1867(c)(l)(A) of the Act if the physician knew, or should have known, that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(3) Misrepresentation made concerning an individual's condition or other information, including a hospital's obligations under section 1867 of the Act.

(c) The OIG may, in lieu of or in addition to any penalty available under this subpart, exclude any responsible physician who commits a gross and flagrant, or repeated, violation of this subpart from participation in Federal health care programs.

(d) For purposes of this subpart, a ''gross and flagrant violation'' is a violation that presents an imminent danger to the health, safety, or well-being of the individual who seeks examination and treatment or places that individual unnecessarily in a high-risk situation.

§ 1003.510 Amount of penalties.

The OIG may impose [5]—

(a) Against each participating hospital, a penalty of not more than $50,000 for each individual violation, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000 for each violation, and

(b) Against each responsible physician, a penalty of not more than $50,000 for each individual violation.

§ 1003.520 Determinations regarding the amount of penalties and the period of exclusion.

In considering the factors listed in § 1003.140,

(a) It should be considered a mitigating circumstance if a hospital took appropriate and timely corrective action in response to the violation. For purposes of this subpart, corrective action must be completed prior to CMS initiating an investigation of the hospital for violations of section 1867 of the Act and must include disclosing the violation to CMS prior to CMS receiving a complaint regarding the violation from another source or otherwise learning of the violation.

(b) Aggravating circumstances include:

(1) Requesting proof of insurance, prior authorization, or a monetary payment prior to appropriately screening or initiating stabilizing treatment for an emergency medical condition, or requesting a monetary payment prior to stabilizing an emergency medical condition;

(2) Patient harm, or risk of patient harm, resulted from the incident; or

(3) The individual presented to the hospital with a request for examination or treatment of a medical condition that was an emergency medical condition, as defined by § 489.24(b) of this title.

Subpart F—CMPs for Section 1140 Violations

§ 1003.600 Basis for civil money penalties.

(a) The OIG may impose a penalty against any person who it determines in accordance with this part has used the words, letters, symbols, or emblems as defined in paragraph (b) of this section in such a manner that such person knew, or should have known, would convey, or in a manner that reasonably could be interpreted or construed as conveying, the false impression that an advertisement, a solicitation, or other item was authorized, approved, or endorsed by the Department or CMS or that such person or organization has some connection with or authorization from the Department or CMS.

(b) Civil money penalties may be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department, or its programs, for misuse of—

(1) The words ''Department of Health and Human Services,'' ''Health and Human Services,'' ''Centers for Medicare & Medicaid Services,'' ''Medicare,'' or ''Medicaid'' or any other combination or variations of such words;

(2) The letters ''DHHS,'' ''HHS,'' or ''CMS,'' or any other combination or variation of such letters; or

(3) A symbol or an emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under Title II, or envelopes or other stationery used by the Department or CMS) or any other combination or variation of such symbols or emblems.

(c) Civil money penalties will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that uses any symbol or emblem or any words or letters that specifically identify that agency or instrumentality of the State or political subdivision.

§ 1003.610 Amount of penalties.

(a) The OIG may impose a penalty of not more than [6]—

(1) $5,000 for each individual violation resulting from the misuse of Departmental, CMS, or Medicare or Medicaid program words, letters, symbols, or emblems as described in § 1003.600(a) relating to printed media;

(2) $5,000 for each individual violation in the case of such misuse related to an electronic communication, Web page, or telemarketing solicitation;

(3) $25,000 for each individual violation in the case of such misuse related to a broadcast or telecast.

(b) For purposes of this paragraph, a violation is defined as—

(1) In the case of a direct mailing solicitation or advertisement, each separate piece of mail that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a);

(2) In the case of a printed solicitation or advertisement, each reproduction, reprinting, or distribution of such item related to a determination under § 1003.600(a);

(3) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under § 1003.600(a);

(4) In the case of an electronic communication, each dissemination, viewing, or accessing of the electronic communication that contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a);

(5) In the case of a Web page accessed by a computer or other electronic means, each instance in which the Web page was viewed or accessed and that Web page contains one or more words, letters, symbols, or emblems related to a determination under § 1003.600(a); and

(6) In the case of a telemarketing solicitation, each individual unsolicited telephone call regarding an item or service under Medicare or Medicaid related to a determination under § 1003.600(a).

§ 1003.620 Determinations regarding the amount of penalties.

(a) In considering the factors listed in § 1003.140, the following circumstances are to be considered—

(1) The nature and objective of the advertisement, solicitation, or other communication and the degree to which it had the capacity to deceive members of the public;

[5] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[6] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

(2) The frequency and scope of the violation and whether a specific segment of the population was targeted; and

(3) The prior history of the individual, organization, or entity in its willingness or refusal to comply with a formal or informal request to correct violations.

(b) The use of a disclaimer of affiliation with the United States Government, the Department, or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.600(a).

Subpart G—[Reserved]

■ 9. Add reserved subpart G.

■ 10. Add subparts H through M to read as follows:

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

Sec.

1003.800 Basis for civil money penalties.
1003.810 Amount of penalties.
1003.820 Determinations regarding the amount of penalties.

Subpart I—CMPs for Select Agent Program Violations

1003.900 Basis for civil money penalties.
1003.910 Amount of penalties.
1003.920 Determinations regarding the amount of penalties.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

1003.1000 Basis for civil money penalties, assessments, and exclusions.
1003.1010 Amount of penalties and assessments.
1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

1003.1100 Basis for civil money penalties.
1003.1110 Amount of penalties.
1003.1120 Determinations regarding the amount of penalties.

Subpart L—CMPs for Drug Price Reporting

1003.1200 Basis for civil money penalties.
1003.1210 Amount of penalties.
1003.1220 Determinations regarding the amount of penalties.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

1003.1300 Basis for civil money penalties.
1003.1310 Amount of penalties.
1003.1320 Determinations regarding the amount of penalties.

Subpart H—CMPs for Adverse Action Reporting and Disclosure Violations

§ 1003.800 Basis for civil money penalties.

The OIG may impose a penalty against any person (including an insurance company) who it determines—

(a) Fails to report information concerning—

(1) A payment made under an insurance policy, self-insurance, or otherwise for the benefit of a physician, dentist, or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist, or other practitioner in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60 or

(2) An adverse action required to be reported under section 1128E, as established by section 221 of Public Law 104–191.

(b) Improperly discloses, uses, or permits access to information reported in accordance with Part B of Title IV of Public Law 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with Part B of Title IV in response to a subpoena or a discovery request is considered an improper disclosure in violation of section 427 of Public Law 99–660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered an improper disclosure in violation of section 427 of Public Law 99–660.)

§ 1003.810 Amount of penalties.

The OIG may impose a penalty of not more than [7]—

(a) $11,000 for each payment for which there was a failure to report required information in accordance with § 1003.800(a)(1) or for each improper disclosure, use, or access to information in accordance with a determination under § 1003.800(b); and

(b) $25,000 against a health plan for each failure to report information on an adverse action required to be reported in accordance with section 1128E of the Act and § 1003.800(a)(2).

§ 1003.820 Determinations regarding the amount of penalties.

In determining the amount of any penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart I—CMPs for Select Agent Program Violations

§ 1003.900 Basis for civil money penalties.

The OIG may impose a penalty against any person who it determines in accordance with this part is involved in the possession or use in the United States, receipt from outside the United States or transfer within the United States, of select agents and toxins in violation of sections 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73.

§ 1003.910 Amount of penalties.

For each individual violation of section 351A(b) or (c) of the Public Health Service Act or 42 CFR part 73, the OIG may impose a penalty of not more than $250,000 in the case of an individual, and not more than $500,000 in the case of any other person.[8]

§ 1003.920 Determinations regarding the amount of penalties.

In considering the factors listed in § 1003.140, aggravating circumstances include:

(a) The Responsible Official participated in or knew, or should have known, of the violation;

(b) The violation was a contributing factor to an unauthorized individual's access to or possession of a select agent or toxin, an individual's exposure to a select agent or toxin, or the unauthorized removal of a select agent or toxin from the person's physical location as identified on the person's certificate of registration; or

(c) The person previously received an observation, finding, or other statement of deficiency from the Department or the Department of Agriculture for the same or substantially similar conduct.

Subpart J—CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

§ 1003.1000 Basis for civil money penalties, assessments, and exclusions.

(a) The OIG may impose a penalty, an assessment, and an exclusion against any person who it determines offers or transfers remuneration (as defined in § 1003.110) to any individual eligible for benefits under Medicare or a State health care program that such person knows, or should know, is likely to influence such individual to order or to receive from a particular provider, practitioner, or supplier, any item or

[7] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[8] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(b) The OIG may impose a penalty against any person who it determines offered any financial or other incentive for an individual entitled to benefits under Medicare not to enroll, or to terminate enrollment, under a group health plan or a large group health plan that would, in the case of such enrollment, be a primary plan as defined in section 1862(b)(2)(A) of the Act.

§ 1003.1010 Amount of penalties and assessments.

The OIG may impose a penalty of not more than [9]—

(a) $10,000 for each item or service for which payment may be made, in whole or in part, under Medicare or a State health care program, ordered by or received from a particular provider, practitioner, or supplier for a beneficiary who was offered or received remuneration in violation of § 1003.1000(a) that was likely to influence the beneficiary to order or receive the item or service from the provider, practitioner, or supplier, and an assessment of not more than 3 times the amount claimed for each such item or service and

(b) $5,000 for each individual violation of § 1003.1000(b).

§ 1003.1020 Determinations regarding the amount of penalties and assessments and the period of exclusion.

In determining the amount of any penalty or assessment or the period of exclusion under this subpart, the OIG will consider the factors listed in § 1003.140, as well as the amount of remuneration or the amount or nature of any other incentive.

Subpart K—CMPs for the Sale of Medicare Supplemental Policies

§ 1003.1100 Basis for civil money penalties.

The OIG may impose a penalty against any person who—

(a) Knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to—

(1) The compliance of any policy with the standards and requirements for Medicare supplemental policies set forth in section 1882(c) of the Act or in promulgating regulations, or

(2) The use of the emblem designed by the Secretary under section 1882(a) of the Act for use as an indication that a policy has received the Secretary's certification;

(b) Falsely assumes or pretends to be acting, or misrepresents in any way that he or she is acting, under the authority of or in association with Medicare or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value;

(c) Knowingly, directly, or through his or her agent, mails or causes to be mailed any matter for the advertising, solicitation, or offer for sale of a Medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance;

(d) Issues or sells to any individual entitled to benefits under Part A or enrolled under Part B of Medicare—

(1) A health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under Medicare or Medicaid,

(2) A health insurance policy (other than a Medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law,

(3) In the case of an individual not electing a Part C plan, a Medicare supplemental policy with knowledge that the individual is entitled to benefits under another Medicare supplemental policy, or

(4) In the case of an individual electing a Part C plan, a Medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Part C plan or under another Medicare supplemental policy;

(e) Issues or sells a health insurance policy (other than a policy described in section 1882(d)(3)(A)(vi)(III)) to any individual entitled to benefits under Medicare Part A or enrolled under Medicare Part B who is applying for a health insurance policy and fails to furnish the appropriate disclosure statement described in section 1882(d)(3)(A)(vii); or

(f) Issues or sells a Medicare supplemental policy to any individual eligible for benefits under Part A or enrolled under Medicare Part B without obtaining the written statement or the written acknowledgment described in section 1882(d)(3)(B) of the Act.

§ 1003.1110 Amount of penalties.

The OIG may impose a penalty of not more than [10]—

(a) $5,000 for each individual violation of § 1003.1100(a), (b), or (c).

(b) $25,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is also the issuer of the policy; and

(c) $15,000 for each individual violation of § 1003.1100(d), (e), or (f) by a seller who is not the issuer of the policy.

§ 1003.1120 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart L—CMPs for Drug Price Reporting

§ 1003.1200 Basis for civil money penalties.

The OIG may impose a penalty against—

(a) Any wholesaler, manufacturer, or direct seller of a covered outpatient drug that—

(1) Refuses a request for information by, or

(2) Knowingly provides false information to, the Secretary about charges or prices in connection with a survey being conducted pursuant to section 1927(b)(3)(B) of the Act; and

(b) Any manufacturer with an agreement under section 1927 of the Act that—

(1) Fails to provide any information required by section 1927(b)(3)(A) of the Act by the deadlines specified therein, or

(2) Knowingly provides any item information required by section 1927(b)(3)(A) or (B) of the Act that is false.

§ 1003.1210 Amount of penalties.

The OIG may impose a penalty of not more than [11]—

(a) $100,000 for each individual violation of § 1003.1200(a) or § 1003.1200(b)(2); and

(b) $10,000 for each day that such information has not been provided in violation of § 1003.1200(b)(1).

§ 1003.1220 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart,

[9] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[10] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

[11] The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

the OIG will consider the factors listed in § 1003.140.

Subpart M—CMPs for Notifying a Skilled Nursing Facility, Nursing Facility, Home Health Agency, or Community Care Setting of a Survey

§ 1003.1300 Basis for civil money penalties.

The OIG may impose a penalty against any individual who notifies, or causes to be notified, a skilled nursing facility, nursing facility, home health agency, a community care setting, of the time or date on which a survey pursuant to sections 1819(g)(2)(A), 1919(g)(2)(A), 1891(c)(1), or 1929(i) of the Act is scheduled to be conducted.

§ 1003.1310 Amount of penalties.

The OIG may impose a penalty of not more than $2,000 for each individual violation of § 1003.1300.[12]

§ 1003.1320 Determinations regarding the amount of penalties.

In determining the amount of the penalty in accordance with this subpart, the OIG will consider the factors listed in § 1003.140.

Subpart N—[Reserved]

■ 11. Add reserved subpart N.

■ 12. Add subpart O to read as follows:

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

Sec.

1003.1500 Notice of proposed determination.
1003.1510 Failure to request a hearing.
1003.1520 Collateral estoppel.
1003.1530 Settlement.
1003.1540 Judicial review.
1003.1550 Collection of penalties and assessments.
1003.1560 Notice to other agencies.
1003.1570 Limitations.
1003.1580 Statistical sampling.
1003.1590 Effect of exclusion.
1003.1600 Reinstatement.

Subpart O—Procedures for the Imposition of CMPs, Assessments, and Exclusions

§ 1003.1500 Notice of proposed determination.

(a) If the OIG proposes a penalty and, when applicable, an assessment, or proposes to exclude a respondent from participation in all Federal health care programs, as applicable, in accordance with this part, the OIG must serve on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure, written notice of the OIG's intent to impose a penalty, an assessment, and an exclusion, as applicable. The notice will include—

(1) Reference to the statutory basis for the penalty, assessment, and exclusion;

(2) A description of the violation for which the penalty, assessment, and exclusion are proposed (except in cases in which the OIG is relying upon statistical sampling in accordance with § 1003.1580, in which case the notice shall describe those claims and requests for payment constituting the sample upon which the OIG is relying and will briefly describe the statistical sampling technique used by the OIG);

(3) The reason why such violation subjects the respondent to a penalty, an assessment, and an exclusion,

(4) The amount of the proposed penalty and assessment, and the length of the period of proposed exclusion (where applicable);

(5) Any factors and circumstances described in this part that were considered when determining the amount of the proposed penalty and assessment and the length of the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of the respondent's right to a hearing and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment, and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the respondent's provider agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the OIG has proposed the imposition of a penalty, an assessment, or an exclusion may appeal such proposed penalty, assessment, or exclusion to the Departmental Appeals Board in accordance with 42 CFR 1005.2. The provisions of 42 CFR part 1005 govern such appeals.

(c) If the respondent fails, within the time period permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

§ 1003.1510 Failure to request a hearing.

If the respondent does not request a hearing within 60 days after the notice prescribed by § 1003.1500(a) is received, as determined by 42 CFR 1005.2(c), by the respondent, the OIG may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, or exclusion. The OIG shall notify the respondent in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty, assessment, and exclusion that have been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, an assessment, or an exclusion with respect to which he or she has not made a timely request for a hearing under 42 CFR 1005.2.

§ 1003.1520 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability for acts that violate this part has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part, a person is estopped from denying the essential elements of the criminal offense if the proceeding—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action.

§ 1003.1530 Settlement.

The OIG has exclusive authority to settle any issues or case without consent of the ALJ.

§ 1003.1540 Judicial review.

(a) Section 1128A(e) of the Act authorizes judicial review of a penalty, an assessment, or an exclusion that has become final. The only matters subject to judicial review are those that the respondent raised pursuant to 42 CFR 1005.21, unless the court finds that extraordinary circumstances existed that prevented the respondent from raising the issue in the underlying administrative appeal.

(b) A respondent must exhaust all administrative appeal procedures established by the Secretary or required by law before a respondent may bring an action in Federal court, as provided in section 1128A(e) of the Act, concerning any penalty, assessment, or exclusion imposed pursuant to this part.

(c) Administrative remedies are exhausted when a decision becomes final in accordance with 42 CFR 1005.21(j).

§ 1003.1550 Collection of penalties and assessments.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the

[12] This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 45 CFR part 102.

case of the Maternal and Child Health Services Block Grant Program, in which the collection will be the responsibility of the Public Health Service (PHS); in the case of the Social Services Block Grant program, in which the collection will be the responsibility of the Administration for Children and Families; and in the case of violations of subpart I, collection will be the responsibility of the Program Support Center (PSC).

(b) A penalty or an assessment imposed under this part may be compromised by the OIG and may be recovered in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The amount of penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States Government or a State agency to the person against whom the penalty or assessment has been assessed.

(d) Matters that were raised, or that could have been raised, in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 1003.1560 Notice to other agencies.

(a) Whenever a penalty, an assessment, or an exclusion becomes final, the following organizations and entities will be notified about such action and the reasons for it: The appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term-care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

(b) When the OIG proposes to exclude a nursing facility under this part, the OIG will, at the same time the facility is notified, notify the appropriate State licensing authority, the State Office of Aging, the long-term-care ombudsman, and the State Medicaid agency of the OIG's intention to exclude the facility.

§ 1003.1570 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.1500(a), within 6 years from the date on which the violation occurred.

§ 1003.1580 Statistical sampling.

(a) In meeting the burden of proof in 42 CFR 1005.15, the OIG may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment, as described in this part, that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment, as described in this part.

(b) Once the OIG has made a prima facie case, as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The OIG will then be given the opportunity to rebut this evidence.

§ 1003.1590 Effect of exclusion.

The effect of an exclusion will be as set forth in 42 CFR 1001.1901.

§ 1003.1600 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of 42 CFR 1001.3001 through 1001.3004.

PART 1005—[AMENDED]

■ 13. The authority citation for part 1005 continues to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

■ 14. Section 1005.4 is amended by republishing paragraph (c) introductory text and revising paragraphs (c)(5) and (6) to read as follows:

§ 1005.4 Authority of the ALJ.

* * * * *

(c) The ALJ does not have the authority to—

* * * * *

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act or under part 1003 of this chapter, or determine the scope or effect of the exclusion;

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case in which the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act or under part 1003 of this chapter; or

* * * * *

Dated: August 3, 2016.

Daniel R. Levinson,

Inspector General.

Approved: August 4, 2016.

Sylvia M. Burwell,

Secretary.

Note: This document was received by the Office of the Federal Register on November 18, 2016.

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Part III

Department of Health and Human Services

Office of Inspector General

42 CFR Parts 1001 and 1003

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1003

RIN 0936–AA06

Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: In this final rule, OIG amends the safe harbors to the anti-kickback statute by adding new safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. The OIG also amends the civil monetary penalty (CMP) rules by codifying revisions to the definition of ''remuneration,'' added by the Balanced Budget Act (BBA) of 1997 and the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010 (ACA). This rule updates the existing safe harbor regulations and enhances flexibility for providers and others to engage in health care business arrangements to improve efficiency and access to quality care while protecting programs and patients from fraud and abuse.

DATES: These regulations are effective on January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Heather L. Westphal, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Social Security Act citation	United States Code citation
1128	42 U.S.C. 1320a–7.
1128A	42 U.S.C. 1320a–7a.
1128B	42 U.S.C. 1320a–7b.
1860D–14A	42 U.S.C. 1395w–114A.
1927	42 U.S.C. 1396r–8.
1102	42 U.S.C. 1302.

Executive Summary

A. Purpose of the Regulatory Action

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and ACA include exceptions to the anti-kickback statute, and the BBA of 1997 and ACA include exceptions to the definition of ''remuneration'' under the civil monetary penalties law. The OIG is codifying those changes here. At the same time, OIG is finalizing additional changes to make technical corrections to an existing regulation and to add new safe harbors to the anti-kickback statute to protect certain services that the industry has expressed an interest in offering and that we believe could be, if properly structured and with appropriate safeguards, low risk to Federal health care programs.

B. Summary of the Major Provisions

1. Anti-Kickback Statute and Safe Harbors

In this final rule, we amend 42 CFR 1001.952 by modifying certain existing safe harbors to the anti-kickback statute and by adding safe harbors that provide new protections or codify certain existing statutory protections. These changes include:

- A technical correction to the existing safe harbor for referral services;
- protection for certain cost-sharing waivers, including:
- pharmacy waivers of cost-sharing for financially needy beneficiaries; and
- waivers of cost-sharing for emergency ambulance services furnished by State- or municipality-owned ambulance services;
- protection for certain remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs);
- protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- protection for free or discounted local transportation services that meet specified criteria.

2. Civil Monetary Penalty Authorities

We amend the definition of ''remuneration'' in the CMP regulations at 42 CFR part 1003 by interpreting and incorporating certain statutory exceptions for:

- Copayment reductions for certain hospital outpatient department services;
- certain remuneration that poses a low risk of harm and promotes access to care;
- coupons, rebates, or other retailer reward programs that meet specified requirements;
- certain remuneration to financially needy individuals; and
- copayment waivers for the first fill of generic drugs.

In addition, because the original language in the introductory paragraph of the definition of ''remuneration'' referred only to ''coinsurance and deductible amounts,'' we have added the word ''copayment'' for consistency with the other text that we proposed and are finalizing.

C. Costs and Benefits

There are no significant costs associated with the regulatory revisions that would impose any mandates on State, local, or tribal governments or on the private sector.

I. Background

A. The Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (the Act), the anti-kickback statute, provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations may also result in the imposition of CMPs under section 1128A(a)(7) of the Act, program exclusion under section 1128(b)(7) of the Act, and liability under the False Claims Act (31 U.S.C. 3729–33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (section 1128B(b)(3)(E) of the Act), which specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be

capable of inducing referrals of business under Federal health care programs. In authorizing the Department of Health and Human Services (Department or HHS) to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended that the safe harbor regulations be updated periodically to reflect changing business practices and technologies in the health care industry.

Section 205 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, established section 1128D of the Act, which includes criteria for modifying and establishing safe harbors. Specifically, section 1128D(a)(2) of the Act provides that, in modifying and establishing safe harbors, the Secretary of Health and Human Services (Secretary) may consider whether a specified payment practice may result in:

- An increase or decrease in access to health care services;
- an increase or decrease in the quality of health care services;
- an increase or decrease in patient freedom of choice among health care providers;
- an increase or decrease in competition among health care providers;
- an increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations;
- an increase or decrease in the cost to Federal health care programs;
- an increase or decrease in the potential overutilization of health care services;
- the existence or nonexistence of any potential financial benefit to a health care professional or provider, which benefit may vary depending on whether the health care professional or provider decides to order a health care item or service or arrange for a referral of health care items or services to a particular practitioner or provider;
- any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.

Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing safe harbors in various areas.[1] These provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.'' (56 FR 35952, 35958 (July 29, 1991)). Many of the safe harbors create new exemptions, while other safe harbors interpret exceptions already promulgated by statute.

Health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. We note, however, that compliance with a safe harbor insulates an individual or entity from liability under the anti-kickback statute and the beneficiary inducements CMP[2] only; individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

Section 101 of the MMA added a new section 1860D to the Act, establishing the Part D prescription drug benefit in the Medicare program. Section 101(e) of the MMA amends section 1128B(b)(3) of the Act to permit pharmacies to waive or reduce cost-sharing imposed under Part D as long as specified conditions are met. In addition, section 237 of the MMA added an exception to permit certain remuneration between MA organizations and FQHCs.

The ACA also includes a number of provisions that could affect liability under the anti-kickback statute. Section 3301 of the ACA establishes the Medicare Coverage Gap Discount Program, codified at section 1860D–14A of the Act. Pursuant to this program, prescription drug manufacturers have entered into agreements with the Secretary to provide certain beneficiaries access to discounts on drugs at the point of sale. Section 3301(d) of the ACA amends the anti-kickback statute to protect the discounts provided for under the Medicare Coverage Gap Discount Program.

In this final rule, we incorporate into our regulations safe harbors for payment and business practices permitted under the MMA and ACA, as well as new safe harbors pursuant to our authority under section 14 of the Medicare and Medicaid Patient and Protection Act of 1987 to protect practices that we view as posing a low risk to Federal health care programs as long as specified conditions are met. We considered the factors cited by Congress in promulgating the safe harbors in this final rule. We believe the safe harbors in this rule further the goals of access, quality, patient choice, appropriate utilization, and competition, while protecting against increased costs, inappropriate steering of patients, and harms associated with inappropriate incentives tied to referrals.

B. Civil Monetary Penalty Authorities

1. Overview of OIG Civil Monetary Penalty Authorities

In 1981, Congress enacted the CMP law, section 1128A of the Act, as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The law authorized the Secretary to impose penalties and assessments on persons who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMP law also authorized the Secretary to exclude persons from Federal health care programs (as defined in section 1128B(f)(1) of the Act) and to direct the appropriate State agency to exclude the person from participating in any State health care programs (as defined in section 1128(h) of the Act). Congress later expanded the CMP law and the scope of exclusion to apply to all Federal health care programs, but the CMP applicable to beneficiary inducements remains limited to Medicare and State health care program beneficiaries. Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse.

2. The Definition of ''Remuneration''

The BBA of 1997 and section 6402(d)(2)(B) of the ACA amended the definition of ''remuneration'' for purposes of the beneficiary inducements CMP at section 1128A(a)(5) of the Act, as discussed below. In this final rule, we are incorporating these changes into the definition of ''remuneration'' under § 1003.110.

C. Summary of the 2014 Proposed Rulemaking

On October 3, 2014, we published in the **Federal Register** (79 FR 59717) a Notice of Proposed Rulemaking (Proposed Rule) setting forth certain proposed amendments to the safe harbors under the anti-kickback statute and proposed amendments to the CMP exceptions. With respect to the anti-kickback statute, we proposed a technical correction to the existing safe harbor for referral services; protection for certain cost-sharing waivers, including pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries and waivers of cost-

[1] 56 FR 35952 (July 29, 1991); 61 FR 2122 (Jan. 25, 1996); 64 FR 63518 (Nov. 19, 1999); 64 FR 63504 (Nov. 19, 1999); 66 FR 62979 (Dec. 4, 2001); 71 FR 45110 (Aug. 8, 2006); 72 FR 56632 (Oct. 4, 2007); 78 FR 78751 (Dec. 27, 2013).

[2] Pursuant to section 1128A(i)(6)(B), a practice permissible under the anti-kickback statute, whether through statutory exception or regulations issued by the Secretary, is also excepted from the beneficiary inducements CMP.

sharing for emergency ambulance services furnished by State- or municipality-owned ambulance services; protection for certain remuneration between MA organizations and FQHCs; protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and protection for free or discounted local transportation services that meet specified criteria. With the exception of the proposed safe harbors for cost-sharing waivers for certain emergency ambulance services and for free or discounted local transportation, all of the proposed safe harbors already were statutory exceptions to the anti-kickback statute (or revisions to existing safe harbors). We proposed five new exceptions to the beneficiary inducements CMP related to copayment reductions for certain hospital outpatient department services; certain remuneration that poses a low risk of harm and promotes access to care; coupons, rebates, or other retailer reward programs that meet specified requirements; certain remuneration to financially needy individuals; and copayment waivers for the first fill of generic drugs. The latter four exceptions emanated from exceptions to the CMP included in the ACA, and some of them included multiple conditions.

We solicited comments on interpretations of each of the anti-kickback safe harbors and CMP exceptions to ensure that we protect low-risk, beneficial arrangements without opening the door to abusive practices that increase costs or compromise patient choice or quality of care.

In the Proposed Rule, we also proposed to add a regulation to reflect section 1128A(b) of the Act (the Gainsharing CMP). The Gainsharing CMP is a self-implementing law that, at the time we issued the Proposed Rule, prohibited hospitals and critical access hospitals (CAHs) from knowingly paying a physician to induce the physician ''to reduce or limit services'' provided to Medicare or Medicaid beneficiaries who are under the physician's direct care, and prohibited the physician from accepting such payments. As we have explained in various guidance documents over the years,[3] the Gainsharing CMP prohibited payments to reduce or limit services, not only payments to reduce or limit ''medically necessary'' services. Without a change in the statute, we continued to believe that we could not read a ''medically necessary'' element into the prohibition. However, in the Proposed Rule, we stated our intention to consider a narrower interpretation of the term ''reduce or limit services'' than we have previously held.

D. Summary of the Final Rulemaking

In finalizing this rule, we are mindful of the impact of delivery system and payment reform on Federal health care programs and the changing relationships between providers in delivering better care, smarter spending, and improved health. Congress intended the safe harbors to evolve with changes in the health care system, and we believe this final rule balances additional flexibility for industry stakeholders to provide efficient, well-coordinated, patient-centered care with protections against fraud and abuse risks. We also believe this rule advances the needs of providers and patients in rural areas and expect that it will have a beneficial effect in promoting improved access to quality care in rural and other underserved areas. The transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers. Many of those new relationships do not implicate our statutes or may be structured to fit in existing exceptions and safe harbors, including those addressed in this final rule. We have taken changes in payment and delivery into account in this final rule. This final rule does not specifically address many emerging arrangements (though, as we note above, some of those arrangements can fit in existing protections). We intend to continue to monitor changes in the industry, technology, and clinical care and consider whether additional rulemaking is needed to foster high-quality, efficient, patient-centered care. We will continue to seek stakeholder input as appropriate, and we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending.

Safe harbors and exceptions, along with advisory opinions, are long-standing tools for addressing the evolution of health care business arrangements under the fraud and abuse laws. More recently, Congress granted the Secretary limited authority to waive certain fraud and abuse laws under Title XI and XVIII of the Act as necessary to carry out and test new payment and delivery models and demonstration programs in Medicare and Medicaid. Specifically, under the ACA, the Secretary has such waiver authority for, among others, the Medicare Shared Savings Program (MSSP) pursuant to section 1899 of the Act and testing models under section 1115A of the Act.[4] This waiver authority creates a new tool for addressing the application of the fraud and abuse laws to business arrangments in a changing health care landscape. Parties participating in these models may use available waivers, if all waiver conditions are met. Alternatively, they are free to look to any available safe harbors or CMP exceptions for protection of arrangements they may undertake. They would not need to comply with both sets of requirements.

We are finalizing all of the anti-kickback statute safe harbors that we proposed, with certain modifications suggested by commenters. We also are finalizing all of the beneficiary inducement CMP exceptions that we proposed. Although we did not propose regulatory text in the Proposed Rule for the exception for remuneration that promotes access to care and poses a low risk of harm, we did propose and solicit comments on interpretations of the statutory terms ''promotes access to care'' and ''low risk of harm'' to programs and beneficiaries. We are finalizing these proposals as regulatory text, as explained in greater detail below. We also note that we are removing the ''or'' that previously appeared between the third and fourth exceptions, now that we are adding five exceptions to the end of the definition of ''remuneration.''

With respect to the Gainsharing CMP, approximately six months after the Proposed Rule was published, Congress amended the law. Congress passed the Medicare and CHIP Reauthorization Act of 2015 (MACRA) in April 2015. Section 512(a) of MACRA amended the language to insert the words ''medically necessary'' before ''services,'' so that now only payments to reduce or limit medically necessary services are prohibited by the law. Because of the amendment to the statute, we are not finalizing the regulation text, as proposed (nor are we finalizing the definition of ''hospital'' that we had proposed adding to section 1003.101 (as proposed to be redesignated as section 1003.110) to complement the Gainsharing CMP proposal). We note that this statutory provision is self-implementing, and no regulatory action is required to make the change enacted

[3] *See, e.g.,* the Special Advisory Bulletin titled ''Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries'', available at: *https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.*

[4] The waivers are posted on the CMS Web site, available at: *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.*

in MACRA effective. However, we may in the future codify the new statutory language in our regulations.

II. Summary of Public Comments and OIG Responses

A. General

We received responsive comments from 88 distinct commenters, including, but not limited to, individuals, trade associations, providers, and suppliers. Many of these individuals and entities provided comments on multiple topics. Commenters generally supported our proposals, but many commenters recommended certain changes or requested certain clarifications. We have divided the public comment summaries and our responses into sections pertaining to the individual safe harbor or CMP exception to which they apply.

B. Anti-Kickback Statute and Safe Harbors

1. Referral Services

We proposed to make a technical correction to the safe harbor for referral services, found at 42 CFR 1001.952(f). In 1999, we finalized a modification to the language of the safe harbor to clarify that the safe harbor precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, *either party for the other party. See* 64 FR 63518, 63526 (Nov. 19, 1999). During subsequent revisions to the safe harbor by which we intended to make a technical correction clarifying that OIG's exclusion authority applied to all Federal health care programs rather than only to Medicare and State health care programs, the language in § 1001.952(f)(2) inadvertently was changed to ''* * * or business otherwise generated by either party for the referral service * * *.'' *See* 67 FR 11928, 11929 and 11934 (Mar. 18, 2002). Therefore, we proposed to make a technical correction and revert to the language in the 1999 final rule cited above. We received no comments on this proposal and intend to make the proposed revision in this Final Rule.

Comment: We received one comment on a different aspect of this safe harbor. A commenter recommended that OIG modernize the safe harbor to permit the use of online, Internet-based tools, as these are the more common modes of communication and can better promote quality patient care.

Response: The commenter's request is outside the scope of this rulemaking. We note, however, that the safe harbor does not exclude the use of online tools. Should we determine in the future that online referral sources need additional or different protection, we may consider revisions to the safe harbor to further facilitate the use of these tools at that time.

2. Cost-Sharing Waivers

While reiterating our concerns about potentially abusive waivers of cost-sharing amounts under the anti-kickback statute, in the Proposed Rule, we proposed to modify § 1001.952(k) by adding two new subparagraphs to protect certain cost-sharing waivers that pose a low risk of harm and make technical corrections to the introductory language to account for new subparagraphs. We also noted that subsection (k) is limited to reductions or waivers of Medicare and State health care program beneficiary cost-sharing and solicited comments about expanding this safe harbor to protect waivers under all Federal health care programs, if applicable, and subject to terms of each type of cost-sharing waiver in subsection (k).

Comment: Several commenters supported the expansion of the safe harbor in subsection (k) of § 1001.952 to protect waivers of cost-sharing obligations for all Federal health care programs. One commenter stated that this expansion would increase patient access to care, treatment, and therapy.

Response: We believe that expanding the scope of subsection (k) to all Federal health care programs, if applicable, is appropriate. We note that subsection (k) protects waivers of specific types of cost-sharing, some of which cannot be read to apply to all Federal health care programs. For example, subparagraph (k)(1) protects only cost-sharing waivers for inpatient hospital services paid on a prospective payment system. Thus, it would protect waivers of cost-sharing of that type, but the safe harbor might not apply to all Federal health care programs due to varying methods of payment. To make this and the change described below, we are republishing subparagraph (k) in its entirety.

Comment: A commenter requested that we change the language in the first sentence of subparagraph (k) from ''coinsurance or deductible'' to ''copayment, coinsurance, or deductible.''

Response: We had proposed to make certain technical corrections to this introductory paragraph to account for the new subparagraphs we proposed to add. Given that we proposed to include the language suggested by the commenter in new subparagraph (k)(3) regarding waivers of Part D cost-sharing, we believe it is reasonable to include this change in the introductory paragraph as well. We have revised the language accordingly in this final rule.

a. Part D Cost-Sharing Waivers

In the Proposed Rule, we proposed a new paragraph at § 1001.952(k)(3) reflecting an exception to the anti-kickback statute at section 1128B(b)(3)(G) of the Act, which was added by section 101 of the MMA. Consistent with the statute, we proposed language that would protect a pharmacy waiving Part D cost-sharing if: (1) The waiver or reduction is not advertised or part of a solicitation; (2) the pharmacy does not routinely waive or reduce the cost-sharing; and (3) before waiving or reducing the cost-sharing, the pharmacy either determines in good faith that the beneficiary is in financial need or the pharmacy fails to collect the cost-sharing amount after making a reasonable effort to do so. If, however, the waiver or reduction of cost-sharing is made on behalf of a subsidy-eligible individual (as defined in section 1860D–14(a)(3) of the Act), then conditions (2) and (3) above are not required. Because the statute incorporates by reference the three conditions stated above from section 1128A(i)(6)(A) of the Act, we proposed to interpret those conditions consistent with our regulations incorporating them in paragraph (1) of the definition of ''remuneration'' at 42 CFR 1003.110. We also cautioned providers, practitioners, and suppliers that safe harbors protect individuals and entities from liability only under the anti-kickback statute and the beneficiary inducements CMP, and that they still must comply with other laws, regulations, and Centers for Medicare and Medicaid Services (CMS) program rules.

Scope of Safe Harbor

Comment: Two commenters requested that the safe harbor for waivers or reductions of Part D cost-sharing obligations by pharmacies be expanded to the Medicaid program. These commenters noted that expanding the safe harbor to Medicaid beneficiaries would benefit low-income patients who often cannot obtain needed health care services because they cannot afford their cost-sharing obligations.

Response: Because we have expanded subsection (k) to apply to all Federal health care programs, where applicable, we have determined that it is appropriate to expand this paragraph as well. Thus, we are not limiting the safe harbor to waivers of Part D cost-sharing. However, we emphasize that this is a safe harbor applicable to pharmacies and does not protect, for example, waivers by physicians for copayments

for Part B drugs. In addition, we are retaining the statutory requirement that pharmacies seeking to rely on this safe harbor may forego the individualized financial need assessment only for subsidy-eligible individuals (as defined in section 1860D–14(a)(3) of the Act).

Comment: One commenter suggested that the proposed safe harbor is more restrictive than the statutory exception. The commenter requested that we expand the safe harbor for waivers of cost-sharing obligations for covered supplies under Part B and for cost-sharing obligations for items and services imposed under Part C. The commenter stated that we have the statutory authority to apply the safe harbor beyond Part D, and asserted that by limiting the safe harbor to Part D plans we would create a competitive disadvantage for MA plans who cannot offer the same ''cost-saving programs.''

Response: We respectfully disagree that the safe harbor that we proposed was more restrictive than the statutory exception; the language of the proposed safe harbor was entirely consistent with the statutory exception. Nevertheless, as we explained above, we are finalizing a safe harbor that protects reductions or waivers by pharmacies of Federal health care program cost-sharing, rather than limiting the protection to waivers of Part D cost-sharing, as long as all requirements of the safe harbor are met.

In addition, we note that this safe harbor is not applicable to anything characterized as a ''cost-saving program'' as we understand the term. This safe harbor permits pharmacies to waive cost-sharing on an unadvertised, nonroutine basis after an individualized determination of financial need (or a failure to collect after reasonable collection efforts). It is not meant to, and would not, protect waivers that are advertised as part of a ''program'' to waive copayments. Finally, the safe harbor protects waivers given at the pharmacy level, not the plan level. Thus, there should be no effect on competition among plans. The safe harbor does not affect the ability of Part D plan sponsors, MA organizations offering Medicare Advantage prescription drug (MA–PD) plans, or other plans to reduce beneficiary cost-sharing obligations as a matter of plan design, nor does it affect their ability to share the cost of such reductions with pharmacies through negotiation of drug prices.

Comment: One commenter suggested that we expand the safe harbor to permit MA plans and pharmacies to develop joint cost-sharing waiver initiatives for dual-eligible beneficiaries and that we allow these waivers for dual-eligible beneficiaries to be routine and advertised. The commenter asserted that its proposed expansion of the safe harbor would be at little or no cost to Federal health care programs.

Response: We decline to accept the commenter's suggestion. The statute expressly states that the waivers cannot be advertised, even for the lowest-income patients. However, as also explained above, MA plans and pharmacies are free to negotiate reduced cost-sharing as part of benefit designs, and MA plans are free to market plan benefits consistent with CMS marketing guidelines.

Comment: One commenter asserted that the regulatory safe harbor does not match the scope of the statute and suggested we broaden the safe harbor to implement congressional intent.

Response: As explained above, despite the fact that we believe the proposed safe harbor was consistent with the statutory language, we have expanded protection in this final rule to include waivers by pharmacies under all Federal health care programs, as long as the waivers meet all elements of the safe harbor.

Advertising

Comment: One commenter expressed concern that the proposed restrictions on advertising and solicitation violate pharmacies' First Amendment rights to free speech, and asserted that these restrictions therefore should be eliminated. As an alternative, the commenter recommended that OIG impose no more than the least restrictive limits on pharmacies' free speech that are necessary to advance a substantial government interest.

Response: The regulatory safe harbor finalized in this final rule is intended to be consistent with subparagraph (G) added to section 1128B(b)(3) of the Act by the MMA. Section 1128B(b)(3)(G) of the Act cites to the conditions specified in clauses (i) through (iii) of section 1128A(i)(6)(A) of the Act. In turn, clause (i) requires that the waiver or reduction of any cost-sharing obligation not be offered as part of any advertisement or solicitation. This prohibition on advertising of covered incentives, waivers, or other item or service has been in the statute since it was enacted in the Health Insurance Portability and Accountability Act of 1996. The safe harbor is consistent with the statutory exception, and we cannot ignore the conditions that Congress explicitly included. Moreover, we do not believe that the restriction on advertising, as a condition of an exception to a statutory provision, is unconstitutional. The exception does not require or prohibit any conduct. Advertising would not violate the anti-kickback statute by itself; any programs that are advertised simply would not be eligible for protection under the exception and would be subject to a case-by-case review under the anti-kickback statute. As explained elsewhere in this rulemaking, our interpretation of the statutory prohibition on advertising is no broader than necessary to preclude communications that create a high risk of abusive steering arrangements under the fraud and abuse laws.

Comment: Several commenters that represent entities such as health centers designated by CMS as FQHCs assert that these types of FQHCs are required by section 330 of the Public Health Service Act to offer a schedule of fees or payments for the provision of their services as well as a corresponding schedule of discounts, which apply on the basis of a patient's ability to pay. In addition, according to the commenters, the Health Resources and Services Administration (HRSA), which administers the Health Center Program, requires these health centers (designated by CMS as FQHCs) to use multiple methods (*e.g.,* signage and registration processes) to inform patients of the sliding fee discount programs. These commenters are concerned that certain activities that are necessary to meet these notification requirements could be construed as advertising, which would exclude these entities from protection under the safe harbor. The commenters suggest clarifying that communications about a FQHC's sliding fee discount program are not an advertisement or solicitation of Part D cost-sharing waivers for purposes of the safe harbor.

Response: We understand HRSA obligates health centers to make patients aware of their sliding fee discount programs, and such communications would not constitute advertising for the purpose of this rule. However, depending where a patient falls on the sliding scale, he or she often still will have a copayment for items or services received at the FQHC. A FQHC would not need to avail itself of this safe harbor for waiving a pharmacy copayment unless it waives the amount that the patient would have been obligated to pay according to the FQHC's sliding scale. That potential waiver would not be protected by the safe harbor if it were advertised.

Comment: Three organizations focused on access to health care for Alaska Natives and American Indians asserted that the restriction on advertisements prohibits providers from informing low-income patients and/or rural patients about affordable health

care options while they are receiving care at a health care facility. According to the commenters, these patients are difficult to contact because they are geographically isolated, elderly, and have limited means of communication, and these patients oftentimes are more likely to forgo services they cannot afford. To address their concerns, the commenters requested that OIG amend the regulation to exclude the following materials from the terms ''advertisement'' and ''solicitation'' for all patients: (1) Information given by a provider to a patient in person; (2) a notice of patient rights on provider Web sites related to charity care or similar opportunities; and (3) any information transmitted directly to a patient as part of a reminder of upcoming appointments or a statement of benefits and coverage.

Response: Although we appreciate the commenters' concerns, we decline to adopt their suggested language narrowing the scope of the terms ''advertisement'' and ''solicitation.'' We agree that it is important for patients to receive information about their health care options, and that not all information provided to beneficiaries is advertising or solicitation. Stakeholders should interpret the terms ''advertisement'' and ''solicitation'' consistent with their common usage in the health care industry. This particular safe harbor relates to cost-sharing waivers by pharmacies. Information posted on Web sites regarding such waivers offered by pharmacies generally would be advertising, while responding to an inquiry from, or discussing financial need with, a particular patient in person generally would not be. However, whether a particular means of communication constitutes an advertisement or solicitation will depend on the facts and circumstances.

''Routine'' Waivers

Comment: One commenter asked us to confirm that a pharmacy does not routinely waive cost-sharing obligations as long as the pharmacy does not automatically waive cost-sharing amounts for beneficiaries of government programs. The same commenter also recommended that OIG exclude any waivers provided to private-pay patients and subsidy-eligible individuals in assessing whether a pharmacy routinely waives cost-sharing obligations. Finally, the commenter suggested that OIG provide flexibility for pharmacies when they establish protocols for employees to use in determining whether a cost-sharing waiver is appropriate. Three commenters asked for clarification as to what constitutes ''routine'' waivers of Part D cost-sharing obligations in the context of FQHCs. According to these commenters, waivers or reductions in cost-sharing obligations under Part D frequently occur at FQHCs because of the low-income populations served at these facilities.

Response: In the Proposed Rule, we explained that we would interpret the conditions in section 1128A(i)(6)(A) of the Act consistent with the regulations interpreting these conditions in paragraph (1) of the definition of ''remuneration'' at § 1003.110. Stakeholders would be well advised to review our guidance on routine waivers of cost-sharing obligations,[5] as well as our guidance on the same condition in the first exception to the definition of remuneration at § 1003.110.[6] First, we do not confirm the commenter's suggestion that waivers are not routine unless they are ''automatic.'' We believe that a waiver or reduction could be common enough to be ''routine'' without being automatic. We decline to adopt the commenter's recommendation to define whether waivers of cost-sharing obligations for private-pay patients and subsidy-eligible individuals count in analyzing whether a pharmacy is routinely waiving Federal health care program cost-sharing obligations. Because of the different makeups of different communities, we do not believe it is appropriate to assign a specific number or percentage of patients to the concept of ''routine.'' While we agree that safe harbor protection would not be denied on the basis of waiving cost-sharing for privately insured or subsidy-eligible patients, if those waivers were advertised as, for example, ''insurance accepted as payment in full,'' then such a program would be suspect. We note, however, that waivers offered to subsidy-eligible patients are exempt from the prohibition against offering routine waivers. This safe harbor sets forth the conditions pharmacies must satisfy to qualify for protection when waiving copayments; we are not mandating (or prohibiting) protocols pharmacies may develop to meet those conditions. Whether a pharmacy waives cost-sharing obligations routinely, and thus fails to satisfy a requirement of the safe harbor, depends on the facts and circumstances. We address waivers by FQHCs in response to a more specific comment above.

[5] *See, e.g.,* Special Fraud Alert, 59 FR 65372 (Dec. 19, 1994), available at *https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[6] 65 FR 24400, 24404 (Apr. 26, 2000).

Financial Need Assessments

Comment: A commenter recommended that OIG provide pharmacies with a uniform, objective standard of financial need to use in meeting the requirement that pharmacies determine in good faith that a beneficiary has a financial need. The commenter requested that we require pharmacies to verify the beneficiary's income (*e.g.,* by reviewing wage statements) prior to waiving his or her Part D cost-sharing obligations. Another commenter requested guidance from OIG as to the methods pharmacies may use to make good faith determinations that individuals are in financial need. According to this commenter, individual assessments are not practical because of the volume of prescriptions that pharmacies dispense, and the commenter asserted that the cost of these individualized assessments would oftentimes be greater than the copayment amount to be waived. For purposes of this safe harbor, the commenter suggested that OIG allow pharmacies to accept as true a patient's statement that he or she is in financial need. Three commenters asked that we confirm that a FQHC's annual assessment of an individual's eligibility for its sliding fee discount program would meet the safe harbor's requirement to make a good faith determination of financial need.

Response: This safe harbor incorporates conditions (i) through (iii) of section 1128A(i)(6)(A) of the Act, and in the Proposed Rule we proposed to interpret them consistent with the regulations interpreting these conditions in paragraph (1) of the definition of ''remuneration'' at § 1003.110. When we finalized that definition, commenters requested guidance as to what constitutes ''financial need,'' and we made the following observations:

> We are not specifying any particular method of determining financial need because we believe what constitutes ''financial need'' varies depending on the circumstances. What is important is that providers make determinations of financial need on a good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases. The guidelines should be based on objective criteria and appropriate for the applicable locality. We do not believe that it is appropriate to apply inflated income guidelines that result in waivers of copayments for persons not in genuine financial need.

65 FR 24404 (Apr. 26, 2000). This guidance applies equally to the same requirement in this safe harbor. We decline to mandate specific guidelines, in part, to permit pharmacies the

flexibility to determine an appropriate method for their patient population and for their business. By way of example only, one pharmacy might choose to apply a multiple of the poverty guidelines, which take into account family size, for determining financial need, while another pharmacy might prefer to take into account a combination of the poverty guidelines, adjusted for the cost of living in the pharmacy's locality, plus family medical expenses. We emphasize, however, whatever guideline is applied by the pharmacy must be reasonable and applied uniformly. If an entity, such as a FQHC, conducts annual assessments of financial need that are performed on a ''good faith, individualized, case-by-case basis in accordance with a reasonable set of income guidelines uniformly applied in all cases,'' then the entity would not need to perform a second assessment to meet this criterion of the safe harbor. Finally, we find it unlikely that the commenter's suggestion that pharmacies that simply accept as true a patient's statement that he or she is in financial need would meet the criteria of an individualized, good faith determination that the patient is in financial need. We understand that there is a cost involved in performing a financial need assessment. We note that pharmacies are not required to waive copayments, nor are they required to perform financial need assessments for subsidy-eligible individuals. For all beneficiaries for whom the pharmacy desires to waive a copayment and be protected by this safe harbor, performing a financial need assessment is an important safeguard. A pharmacy might do this by verifying each applicant's financial resources through information provided by a third party service, collecting documentation of financial need from the applicant (*e.g.,* pay stubs, tax forms, or evidence of other expenses), or some combination thereof. While we are not requiring any specific documentation of financial need, we do expect that entities offering these reductions or waivers would do so in accordance with a set policy that is reasonable and uniformly applied. Moreover, if an entity were under investigation and asserted this exception as a defense, it would have to be able to demonstrate compliance with the requirement to make an individualized, good faith determination of financial need. A written policy describing the reasonable standards and procedures used for establishing financial need, together with evidence that this written policy was followed, would be useful in making such a demonstration.

Reasonable Collection Efforts

Comment: Under the second option in subsection (3)(ii)(B) of the safe harbor, a pharmacy must fail to collect the copayment, coinsurance, or deductible after making reasonable collection efforts. One commenter asserted that the '' reasonable collection efforts'' standard should account for the fact that many cost-sharing obligations are small and the costs associated with collection efforts would exceed the amount owed by the beneficiary. The commenter suggested that pharmacies be able to forgo collection efforts and still meet this condition of the safe harbor if the beneficiary has a ''smaller than average'' cost-sharing amount or when past collection efforts indicate the costs of collection efforts are greater than the projected recovery amounts.

Response: Like the requirement for a pharmacy to conduct a good faith determination of a beneficiary's financial need, we indicated that we would interpret the reasonable collection efforts requirement consistent with our regulations interpreting that same condition in paragraph (1) of the definition of ''remuneration'' at § 1003.110. In previous guidance on this condition, we stated that '' 'reasonable collection efforts' are those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients.'' 65 FR 24404 (Apr. 26, 2000). In other contexts, we also have cited to the CMS Provider Reimbursement Manual's description of ''reasonable collection efforts,'' which requires providers to issue a bill for the patient's financial obligations, and also includes: ''other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort.'' [7] These concepts apply to this new safe harbor. We note that we cannot envision a scenario in which a preemptive decision by a pharmacy not to request payment from a patient (in the absence of a determination of financial need) or pursue any collection efforts could meet this condition. The amount of the copayment or historical inability to collect cost-sharing amounts for a particular beneficiary might be factors that are considered in determining what reasonable collection efforts are, but they do not justify forgoing all collection efforts.

[7] *See* Provider Reimbursement Manal (CMS Pub. 15–1) § 310.

Comment: According to three commenters, Indian Health Service (IHS) facilities are statutorily prohibited from charging cost-sharing amounts to Alaska Natives and American Indians, and the commenters further state that tribal health programs do not charge any cost-sharing amounts to Alaska Natives and American Indians ''on principle.'' These commenters are concerned that creating a narrow safe harbor for pharmacies (and for ambulance services in subsection (4)) to waive or reduce cost-sharing obligations implies that tribal health programs are violating the Federal anti-kickback statute if they waive cost-sharing obligations for Alaska Natives and American Indians in other situations. The commenters requested that OIG include language in the safe harbor that would permit facilities operated by IHS, an Indian tribe, a tribal organization, or an urban Indian organization to waive cost-sharing amounts for any individual eligible to receive services from IHS and still comply with the Federal anti-kickback statute.

Response: The language requested by the commenters regarding cost-sharing waivers for other services is outside the scope of this rulemaking. This safe harbor is limited to implementing the exception in subparagraph (G) of section 1128B(b)(3) of the Act, which includes waivers or reductions of cost-sharing obligations imposed by pharmacies of IHS, Indian tribes, tribal organizations, and urban Indian organizations. We note, however, that if an entity is statutorily prohibited from collecting a copayment from a particular patient, there is no copayment to be ''waived'' and thus no protection needed for a copayment waiver.

Comment: A commenter requested clarification that § 1001.952(k)(3) applies to reductions of cost-sharing obligations, not just waivers.

Response: We agree with the commenter that subsection (3) applies to waivers or reductions of copayments, coinsurance, or deductible amounts, and we have revised the text accordingly.

b. Cost-Sharing Reductions or Waivers for Emergency Ambulance Services

We proposed to establish a safe harbor to protect reductions or waivers of cost-sharing owed for emergency ambulance services for which Medicare pays under a fee-for-service payment system and meets the following conditions: (1) The ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a federally recognized Indian tribe; (2) the ambulance provider or supplier is the

Medicare Part B provider or supplier of the emergency ambulance services; (3) the reduction or waiver is not considered the furnishing of free services paid for directly or indirectly by a government entity; (4) the ambulance provider or supplier offers the reduction or waiver on a uniform basis, without regard to patient-specific factors; and (5) the ambulance provider or supplier does not later claim the amount reduced or waived as bad debt or otherwise shift the burden to Medicare, a State health care program, other payers, or individuals. We solicited comments on these criteria and related issues. We are finalizing certain aspects of the rule as we proposed it, but we are making certain modifications in response to comments that we received.

Owned and Operated by the State

We proposed to require that the ambulance provider or supplier be owned and operated by a State, a political subdivision of a State, or a federally recognized Indian tribe [8] and be the Medicare Part B provider or supplier of the emergency ambulance services. We also proposed to limit the safe harbor protection to situations in which a provider's or supplier's reduction or waiver of cost-sharing amounts is not considered to be the furnishing of services paid for directly or indirectly by a government entity,[9] subject to applicable exceptions promulgated by CMS. We solicited comments on these conditions.

Comment: Two commenters noted that the proposed waiver excluded ambulance services operated by tribal organizations authorized by federally recognized Indian tribes to carry out health programs on their behalf. The commenters stated that the Indian Self-Determination and Education Assistance Act (ISDEAA) permits Indian tribes to authorize tribal organizations and inter-tribal consortiums to carry out ISDEAA functions, which can include ambulance services. The commenters noted that tribal health organizations might be the only ambulance providers or suppliers in a tribal area. Thus, the commenters recommended using the phrase ''tribal health program, as that term is defined in section 4 of the Indian Health Care Improvement Act'' (25 U.S.C. 1603) instead of ''federally recognized Indian tribe.''

Response: We are accepting the commenter's recommendation and have revised the text accordingly. The ambulance services described by the commenters are the type that we intended to protect when we proposed to protect ambulance providers or suppliers owned and operated by a federally recognized Indian tribe.

Comment: Some commenters requested that we expand the safe harbor to include nongovernmental ambulance providers or suppliers under certain conditions. Some commenters requested that we protect nongovernmental ambulance providers or suppliers when they contract with a State or municipality, and the State or municipality pays the cost-sharing amounts otherwise due from beneficiaries to the ambulance company through an actuarially determined amount of the residents' tax revenues. Another commenter asked us to protect nonprofit ambulance companies that otherwise comply with the safe harbor if they operate a waiver program under which beneficiaries pay an annual subscription fee that reasonably approximates what the ambulance company would have collected in cost-sharing amounts from subscribers. Another commenter requested that we protect hospital ambulance services that provide emergency transports.

Response: We are finalizing our requirement (with the amendment discussed above) that protects only ambulance providers and suppliers owned and operated by a State, a political subdivision of a State, or tribal health program, as that term is defined in section 4 of the Indian Health Care Improvement Act. As we explained in the preamble to the Proposed Rule, municipalities cannot contract with private ambulance companies and require them to waive their residents' cost-sharing. However, when a State or municipality contracts with a private ambulance company, and the State or municipality uses its residents' tax dollars to pay the ambulance company an amount that is actuarially equivalent to the residents' copayments, the anti-kickback statute would not be implicated. For an example of such an arrangement, please see OIG Advisory Opinion No. 13–11. If the anti-kickback statute is not implicated, no safe harbor is necessary. Subscription arrangements referenced by the other commenter are distinct from arrangements in which the State or municipality pays the ambulance company. We believe that these arrangements should be subject to a case-by-case determination, rather than protected by a safe harbor. Moreover, we did not contemplate these arrangements in the Proposed Rule and therefore could not finalize any regulatory text to protect them, even if we believed they should be protected. Likewise, we did not propose to protect waiver of cost-sharing by hospital-operated ambulance services.

Not Furnishing Free Services

We proposed to include a requirement that the reduction or waiver not be considered the furnishing of free services paid for directly or indirectly by a government entity. We explained that items or services that are paid for directly or indirectly by a government entity generally are not reimbursable by Medicare. CMS has a policy holding that State or local government facilities (including ambulance providers or suppliers) that reduce or waive charges for patients unable to pay, or charge patients only up to their Medicare and other health insurance coverage, are not considered to be providing free services. We proposed to incorporate this condition into the safe harbor. In response to the following comment, we are modifying this condition.

Comment: One commenter suggested that we eliminate the condition related to the waiver not constituting free services paid for by a government entity. The commenter gave several reasons for this recommendation, including the commenter's belief that inclusion of the requirement is superfluous, that ambulance providers and suppliers should not have to review authority quoted in other sources (such as advisory opinions) to interpret a rule, and that the language is vague.

Response: We agree with the commenter's recommendation to an extent, but we reach our conclusion for different reasons. As the commenter correctly states, several of our advisory opinions regarding ambulance cost-sharing waivers include the cited language from CMS guidance. In the context of an advisory opinion, we generally are analyzing an arrangement that potentially implicates a fraud and abuse statute, such as the anti-kickback statute, but may not fit into an exception or safe harbor. As we stated in one such opinion, OIG Advisory Opinion No. 06–07, ''since Medicare would not require the Municipal Ambulance Provider to collect cost-sharing amounts from municipal residents, we would not impose sanctions under the anti-kickback statute where the cost-sharing waiver is implemented by the Municipal Ambulance Provider categorically for bona fide residents of the Municipality.'' In other words, we relied on CMS guidance to ensure that the arrangement we approved was low

[8] Section 104 of the Federally Recognized Indian Tribe List Act of 1994, Public Law 103–454, 108 Stat. 4791, requires the Secretary to publish a list of all federally recognized Indian tribes on an annual basis.

[9] *See* 42 CFR 411.8.

risk. In the context of a safe harbor, however, while we need not rely on other guidance, we also want to ensure that the conduct we are protecting is low risk and does not permit a practice that would be prohibited by a different law. Because we understand the conduct does not violate CMS requirements, as long as ambulance providers and suppliers are in compliance with the other provisions of this safe harbor, we believe this condition can be removed.

Offered on a Uniform Basis Without Regard to Patient-Specific Factors

We proposed to require that the ambulance provider or supplier offer the reduction or waiver on a uniform basis, without regard to patient-specific factors. We are finalizing this condition, with certain textual revisions for additional clarity.

Comment: We received one comment recommending that we eliminate the phrase ''without regard to patient-specific factors.'' The commenter suggested that OIG did not enumerate what such factor could be, and that the phrase is ambiguous.

Response: While we agree that we did not provide a list of patient-specific factors in the Proposed Rule, we decline to eliminate the concept from the safe harbor. However, we have modified the language, as explained below. This condition includes two prongs that should be read together: The waivers must be offered on a uniform basis, and the waivers (and the policy) should not be based on patient-specific factors. We intended ''patient-specific factors'' to include anything other than residency in the municipality or other governmental unit providing the ambulance service. We understand from the many advisory opinions we have issued in this context that tax revenue from residents is often attributed to cover residents' cost-sharing. We clarified the text of the final rule to eliminate any confusion on that point: an ambulance provider or supplier could waive cost-sharing amounts for all residents, but charge cost-sharing amounts to nonresidents. However, the ambulance provider or supplier cannot discriminate on the basis of any factor other than residency or, if applicable, tribal membership. For example, an ambulance provider or supplier cannot waive cost-sharing amounts for patients transported for an emergency that required only outpatient treatment, but charge cost-sharing amounts for patients transported for a condition that requires hospitalization (or vice versa). They cannot choose whether to waive cost-sharing on the basis of the patient's age. Under this particular safe harbor, they cannot waive cost-sharing on the basis of insurance or financial status. In other words, this safe harbor protects only routine waivers of cost-sharing by the entities specified, where the waivers do not take into account or require any case-by-case, patient-specific determinations (other than residency or tribal membership, as explained above).

No Cost-Shifting

We proposed to prohibit claiming the amount reduced or waived as bad debt for payment purposes under Medicare or a State health care program or otherwise shifting the burden of the reduction or waiver to Medicare, a State health care program, other payers, or individuals.

Comment: One commenter asked OIG to clarify what activities would be considered to be cost-shifting. The commenter suggested that ambulance providers or suppliers do not appear to have an opportunity to shift costs to Medicare, because Part B emergency ambulance services are paid on a fee-for-service basis. The commenter also requested clarification that prohibited ''cost-shifting'' would not include differentials in payment amounts based on a fee schedule (*e.g.,* if a private insurer pays more for emergency ambulance transports than Medicare pays).

Response: First, we confirm that commenter's understanding that accepting a higher fee schedule amount from a private insurer would not constitute cost-shifting (assuming the fee schedule is either a standard fee schedule for the insurer or was not specifically requested by the ambulance provider or supplier to recoup costs it may lose by waiving copayments). As for the larger question of cost-shifting, we can imagine many ways an ambulance provider or supplier could shift costs to a Federal health care program (*e.g.,* by upcoding services, providing medically unnecessary services, or other illegal or inappropriate means). While each method of cost-shifting or making up for costs could be an independent ground for sanctions, we include it in the safe harbor to clarify that it would also result in the copayment waivers losing protection.

Definitions

For purposes of this safe harbor, we proposed to interpret the term ''ambulance provider or supplier'' as a provider or supplier of ambulance transport services that furnishes emergency ambulance services, which would not include a provider or supplier of ambulance transport services that furnishes only nonemergency transport services. We proposed to interpret ''emergency ambulance services'' in a manner consistent with the definition given to that term in 42 CFR 1001.952(v)(4)(iv). After considering comments received, we are finalizing modified versions of these definitions.

Comment: One commenter recommended that we expressly include ambulance providers and suppliers that are enrolled in Part A as well as Part B of Medicare.

Response: We decline to adopt the commenter's specific recommendation. We understand that emergency ambulance services, as we use that term in this regulation, are covered under Part B. However, with respect to the Medicare program, Part A could cover transportation between facilities and not generally emergency calls that would result in service by the types of ambulance providers and suppliers included in this safe harbor. As we explain below, however, we are expanding this safe harbor to include other Federal health care programs. Thus, we are removing the clause that specified that the ambulance provider or supplier be the Medicare Part B provider or supplier of emergency ambulance services.

Comment: One commenter suggested relying on a different definition for ''emergency ambulance services.'' Rather than cross-referencing a definition found in another safe harbor, the commenter recommended using the following definition of ''emergency response'' found in Medicare regulations: ''Emergency response means responding at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.'' 42 CFR 414.605. The commenter recommended revising the condition regarding emergency ambulance services as follows: ''The ambulance provider or supplier is the Medicare Part B provider or supplier of the emergency ambulance services, meaning the provider or supplier engaged in an emergency response, as defined in 42 CFR 414.605.''

Response: We had solicited comments about interpreting ''emergency ambulance services'' in a manner consistent with the definition given to that term in 42 CFR 1001.952(v)(4)(iv). We believe that the commenter provided a helpful recommendation that we are incorporating into this final rule.

We agree that it makes more sense to include a definition directly within the text of this safe harbor, and that the definition proposed by the commenter, while capturing similar elements to the definition we proposed, is more aligned with the purpose of this safe harbor than the definition we proposed.

Comment: One commenter requested that we protect psychiatric emergency transportation. Another commenter requested protection for cost-sharing waivers for ambulance transports that do not qualify as ''emergency'' transports, but that are initiated based on a provider's judgement that the patient requires specialized transportation.

Response: We decline to expand the safe harbor to protect cost-sharing waivers for either of these suggested forms of transportation, to the extent that the transports do not meet the definition of ''emergency response'' set forth in the regulation. As a threshold matter, we did not propose either of the suggested policies. The safe harbor is limited to waivers for emergency transports, and we believe waivers in connection with nonemergency transports are too high risk to be protected by a safe harbor at this time. We note, however, that the regulation does not necessarily exclude transportation of psychiatric patients. For example, if a psychiatric patient is a threat to himself, herself, or others, and an emergency transport is necessary (to a hospital emergency department or psychiatric hospital), cost-sharing waivers for the transportation could be protected.

Expansion to Other Federal Health Care Programs

We solicited comments about whether to include reductions or waivers of cost-sharing amounts owed under other Federal health care programs (*e.g.,* Medicaid) in the safe harbor. We are finalizing a safe harbor that includes such reductions and have made appropriate modifications to the proposed regulation.

Comment: Several commenters supported expanding the safe harbor to apply to waivers of cost-sharing owed under other Federal health care programs, especially Medicaid. Commenters suggested that such an expansion would allow ambulance providers and suppliers to treat all patients equally. Certain commenters note that IHS facilities are statutorily prohibited from charging copayments to Alaska Natives and American Indians, and tribal health programs do not charge such amounts to Alaska Natives and American Indians on principle. The commenters asked that we clarify that those waivers do not violate the anti-kickback statute.

Response: We agree with the commenters that requested expansion of protection to all Federal health care program beneficiaries. We see no greater risk under the anti-kickback statute in allowing such waivers for beneficiaries of other programs, if they are allowed for Medicare beneficiaries. We note, however, the safe harbor protects practices only under the Federal anti-kickback statute; to the extent that such waivers are prohibited under a payment policy or other law or regulation (*e.g.,* a particular State Medicaid program), this safe harbor would provide no protection for violations of those laws, regulations, or requirements. With respect to the prohibition on IHS facilities charging cost-sharing to Alaska Natives and American Indians, as we explain in response to a similar comment above, if an entity is statutorily prohibited from collecting a copayment from a particular patient, there is no copayment to be ''waived.''

Textual Revisions

We received comments regarding two omissions in the Proposed Rule: (1) We inadvertently omitted ''provider or'' from the proposed text of subparagraph (iv); and (2) we inadvertently omitted tribes in one of the descriptions of ambulances operated by a State or a political subdivision of a State. We confirm that these were inadvertent and are corrected, as applicable, in this final rule.

3. Federally Qualified Health Centers and Medicare Advantage Organizations

We proposed to incorporate into our safe harbors a statutory exception to the anti-kickback statute at section 1128B(b)(3)(H) of the Act, which was added by section 237 of the MMA. This exception protects ''any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a MA organization pursuant to a written agreement described in section 1853(a)(4) [of the Act].'' Section 1853(a)(4) of the Act (which should be read in conjunction with section 1857(e)(3) of the Act, as described below) generally describes the payment rule for FQHCs that provide services to patients enrolled in MA plans that have an agreement with the FQHC. We are finalizing the language that we proposed. Commenters generally supported the safe harbor, and specific comments are addressed below.

Comment: One commenter did not support the Medicare requirement for MA plans to pay FQHCs at the same level and amount that they pay other providers. The commenter states that each provider gets different rates based on a variety of different factors, and the commenter does not support limiting the ability of a MA plan to weigh those factors and determine payment rates.

Response: This comment is outside the scope of this rulemaking. The commenter is referencing a payment rule, while this rule relates to protecting certain remuneration under the anti-kickback statute.

Comment: One commenter supports the safe harbor, but recommends two qualifications: (1) That the level and amount of payment to the FQHC not exceed levels or amounts for similar providers; and (2) that the safe harbor also apply to remuneration and payment whether the services are provided at the FQHC or by a provider who contracts to provide services through a contract with the FQHC.

Response: With respect to the first suggestion, the safe harbor protects remuneration paid pursuant to an agreement described in section 1853(a)(4) of the Act between a MA organization and a FQHC. Section 237 of the MMA specifies that agreements described in section 1853(a)(4) must provide for a level and amount of payment to the FQHC that is not less than the level and amount of payment that the MA organization would make for such services if the services had been furnished by an entity other than a FQHC. The safe harbor protects payments made pursuant to such agreements, and the law sets a minimum, but not a maximum, payment level to be specified in the applicable agreements. The additional qualification suggested by the commenter varies from this statutory requirement. With respect to the second suggestion, the statute specifically applies to remuneration between FQHCs and MA organizations that have certain written contracts; it does not reach remuneration between FQHCs and third-parties. However, if the arrangement between the FQHC and the third-party provider is consistent with the requirements of section 1853(a)(4), the fact that the services were provided by a third-party entity would not disqualify the remuneration between the FQHC and the MA organization from protection under the safe harbor.

Comment: Two commenters request that we clarify whether four specific types of arrangements would be protected under this safe harbor: (1) All remuneration between a MA organization and a health center, without regard to amounts typically paid to other providers or fair market

value; (2) the provision of free space by the FQHC to the MA organization (*e.g.,* free conference room space for the MA organization to offer sales presentations to potential enrollees); (3) financial support from the MA organization to the FQHC (*e.g.,* for conducting outreach activities, purchasing health information technology, and funding infrastructure costs), even when the support is based on the number of health center patients enrolled in the MA organization; and (4) remuneration between a health center and an IPA when the IPA stands in the shoes of the MA organization pursuant to an indirect contract arrangement between a health center and MA organization recognized by CMS regulations.

Response: Some of these examples would be protected by the safe harbor, but others would not be. We reiterate, however, that not every arrangement between two parties implicates the anti-kickback statute. If an arrangement does not implicate the statute, then no safe harbor is necessary to protect it. Moreover, entities seeking to provide remuneration to a FQHC should also consider whether the safe harbor at 42 CFR 1001.952(w), which addresses transfers of certain items, services, goods, donations or loans to FQHCs, could apply. With that said, we address the potential protection of each example under this safe harbor in turn.

The first example could be protected under this safe harbor, if the commenter's use of the term ''all remuneration'' is understood in the context of what the safe harbor protects (payment for certain FQHC services). The statutory exception was added by section 257(d) of the MMA. Section 257(c) of the MMA specified the following payment rule (added in 1857(e)(3)): ''in any written agreement described in section 1853(a)(4) between [an MA organization] and [FQHC], for a level and amount of payment to the [FQHC] for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by [an] entity providing similar services that was not a [FQHC].'' The statute does not include a fair market value requirement; it provides for a minimum level of payment by the MA organization. Thus, the safe harbor protects payment for FQHC services that meet this requirement. It does not, however, protect ''all remuneration'' that the parties might exchange. The second example of remuneration—providing free space—would not be protected by this safe harbor. The safe harbor protects payments related to FQHCs treating MA plan enrollees, not arrangements unrelated to MA plan enrollees being treated at the FQHC. The same analysis applies to the third example: Financial support for the FQHC is outside the scope of what the safe harbor protects. Finally, we confirm that the fourth example would come within the ambit of the safe harbor with respect to the requirement that the FQHC have a written agreement with the MA plan. CMS has interpreted the requirements related to services provided to MA plan enrollees as including indirect contracts. Specifically, in a 2005 final rule, CMS stated: ''[w]e interpreted section 237 of the MMA to mean that any Medicare FQHC furnishing covered FQHC services to MA plan enrollees would be eligible for supplemental payments regardless of whether they have a direct contract with a MA organization or contract with another entity (for example, a medical group) that has a direct contract with the MA organization to treat its enrollees.'' 70 FR 70116, 70268 (Nov. 21, 2005). Because this safe harbor is in place largely because of a payment rule, we believe it is reasonable to rely on the interpretations applicable to that payment rule.

4. Medicare Coverage Gap Discount Program

Section 3301 of the ACA establishes the Medicare Coverage Gap Discount Program, codified at section 1860D–14A of the Act. Under this program, prescription drug manufacturers enter into an agreement with the Secretary to provide certain beneficiaries access to discounts on drugs at the point of sale. Section 3301(d) of the ACA amends the anti-kickback statute by adding a new subparagraph (J) to section 1128B(b)(3) of the Act to protect the discounts provided for under the Medicare Coverage Gap Discount Program, which we proposed to incorporate into our safe harbor regulations.

We proposed to protect a discount in the price of an ''applicable drug'' of a manufacturer that is furnished to an ''applicable beneficiary'' under the Medicare Coverage Gap Discount Program under section 1860D–14A, as long as the manufacturer participates in and is in full compliance with all requirements of the Medicare Coverage Gap Discount Program. We proposed to incorporate by reference the definitions of the terms ''applicable beneficiary'' and ''applicable drug'' that were added by a new section 1860D–14A(g) of the Act. Commenters generally supported our proposal. Specific comments and recommendations are addressed below.

Comment: Some commenters noted that a safe harbor is unnecessary, because the statutory exception is sufficient.

Response: We acknowledged in the Proposed Rule that the statutory exception was self-implementing. However, for the sake of completeness, we generally incorporate and interpret statutory exceptions in our safe harbor regulations.

Comment: Several commenters objected to our proposal to require that manufacturers be ''in full compliance with all requirements of'' the Medicare Coverage Gap Discount Program to qualify for safe harbor protection. Commenters expressed concern that minor administrative or technical non-compliance could open manufacturers up to liability. For example, one commenter provided hypotheticals under which a manufacturer met all requirements, except did so one day late. A commenter suggested that neither the ACA nor the anti-kickback statute support the requirement that a manufacturer be in compliance with the all requirements of the program. Another commenter asserted that we exceeded our rulemaking authority by including this requirement.

Response: Although we disagree with the commenter who asserted that we do not have the authority to require compliance with the very program that this safe harbor aims to protect, we do agree with commenters who suggested that minor, technical instances of non-compliance should not preclude safe harbor protection. Thus, we are revising the language to reflect that manufacturers must be in compliance with the Medicare Coverage Gap Discount Program. While we do not contemplate that missing a payment deadline by one day would subject a manufacturer to sanctions under the anti-kickback statute, the safe harbor only protects discounts offered in connection with this program. A manufacturer that knowingly and willfully provided discounts without complying with the requirements of the Medicare Coverage Gap Discount Program could be subject to sanctions, unless such discounts are protected by another safe harbor.

Comment: One commenter suggested that the definitions of ''applicable beneficiary'' and ''applicable drug'' are too narrow, because they apply only to beneficiaries enrolled in, and drugs that are covered by, prescription drug plans and MA–PD plans. The commenter asserts that the exception should be expanded to encompass Medicare reasonable cost contractors under

section 1876 of the Act that offer a Part D supplemental benefit.

Response: We decline to adopt the commenter's suggestion at this time. We proposed to incorporate the statutory definitions used in establishing the Medicare Coverage Gap Discount Program into the safe harbor regulation, and we intend to rely on those definitions.

5. Local Transportation

Pursuant to our authority at section 1128B(b)(3)(E) of the Act, we proposed to establish a new safe harbor at 42 CFR 1001.952(bb) to protect free or discounted local transportation services provided to Federal health care program beneficiaries.

In the Proposed Rule, we proposed to protect free or discounted local transportation made available by an ''eligible entity'' to established patients (and, if needed, a person to assist the patient) to obtain medically necessary items or services. We also sought comments on a second form of transportation that would be akin to a shuttle service. We proposed a number of conditions on offering or providing protected free or discounted local transportation services, and proposed definitions of certain terms, such as ''eligible entity,'' ''established patient,'' and ''local.'' Overall, we received substantial support for implementing a safe harbor to protect local transportation. Many commenters urged us to include (or decline to include) certain safeguards within the final regulation. With certain modifications described below in response to the comments we received, we are finalizing a safe harbor at § 1001.952(bb) for local transportation for established patients.

General Comments

We received a number of comments generally in support of the proposed safe harbor, and others requesting specific changes or clarifications.

Comment: Several commenters expressed general support for the concept of free or discounted local transportation, and for proposing it as a safe harbor that would cover all Federal health care program beneficiaries. Commenters stated the proposal would increase access to care. Commenters gave examples of patients who would benefit, such as those who cannot drive or take public transportation after a procedure, or isolated/homebound patients. One commenter noted that Congress expressly stated that the beneficiary inducement prohibition was not intended to prohibit complimentary local transportation and urged OIG to consider the needs of certain patient populations (like mental health and substance abuse patients). One commenter supported our proposal to eliminate the nominal value restriction with respect to transportation.

Response: We acknowledged in the Proposed Rule that Congress did not intend to preclude the provision of local transportation of nominal value in the context of the beneficiary inducements CMP. (*See* 79 FR 59717, 59721). However, the anti-kickback statute does not have any exceptions for items or services of nominal value. With that clarification, we agree that a safe harbor is warranted to protect complimentary local transportation that meets certain requirements that limit the risk of fraud and abuse.

Comment: One commenter recommended that we cover transportation whether planned in advance or for ad hoc services that arise unexpectedly, and whether provided directly or through vouchers. Other commenters requested that we expressly state that the safe harbor also protects transportation back to a patient's home.

Response: We agree with the commenters. First, the safe harbor would protect transportation both to a provider or supplier of services and back to a patient's home, as long as all conditions of the safe harbor are met. Next, an eligible entity offering free or discounted local transportation need not require that transportation be planned in advance. Further, a transportation program could use vouchers rather than having the transportation provided directly by the eligible entity. However, we reiterate that the transportation cannot take the form of air, luxury, or ambulance-level service and must meet other requirements described herein to be protected under the safe harbor.

Comment: One commenter requested that OIG clearly define the situations in which free transportation can be provided and clearly outline the process for determining patient eligibility.

Response: We have set out the conditions under which free transportation will be protected in this final rule. We have provided explanations of each condition, and examples where we believe them to be helpful. Individuals and entities seeking to offer transportation and be protected by the safe harbor should apply these conditions and guidance to their desired program. We decline to mandate specific eligibility terms or a set list of situations under which transportation would be protected, beyond what we specify in this final rule.

Comment: One commenter recommended a more narrowly defined safe harbor, particularly with respect to dialysis providers. The commenter expressed concern that larger, well-funded dialysis providers may increase their volume by routinely providing transportation, thus hurting smaller providers. The commenter recommended protecting transportation for dialysis patients only on an infrequent basis and in accordance with policies that the commenter believes the OIG should clearly outline. Some commenters asked that we clearly state that dialysis facilities would not be required to provide free transportation. Other commenters recommended that dialysis facilities should be allowed to offer transportation only in certain circumstances, such as when a beneficiary suddenly finds him- or herself without transportation to or from a dialysis facility, for beneficiaries with intermittent lack of reliable transportation, or for certain emergent purposes.

Response: First, we reiterate that safe harbors are voluntary. This safe harbor does not require any individual or entity to offer free or discounted local transportation services; it sets forth conditions and limitations on providing such transportation. With respect to the other comments in the paragraph above, we decline to adopt the commenters' suggestions. We do not believe that this safe harbor should have additional restrictions tailored to a specific patient population, such as dialysis patients. Any time a provider or supplier is permitted to give something for free or reduced cost to beneficiaries, there is a risk that such a program will affect competition, because entities with greater financial resources might be in a better position to provide the ''extras.'' However, we believe that the combination of requirements in the safe harbor will mitigate that risk and appropriately balances the risks against the potential benefits of a well-designed and properly structured transportation program. For example, the prohibition on advertising constrains the use of free or discounted transportation as a marketing tool, and the mileage limitations serve to limit, to some degree, the cost of the transportation provided. In addition, we believe this safe harbor will save Federal health care programs money in the very population cited by the commenter; dialysis patients are a population that has been identified as contributing to the increasing costs of nonemergency ambulance transportation and would

benefit from local transportation furnished by providers.[10]

Comment: One commenter was concerned that eligible entities might demand concessions from their existing transportation vendors, despite the prohibitions on cost-shifting. The commenter requested that we clarify that contracts between eligible entities and transportation vendors are subject to existing ''OIG guidelines.''

Response: While we are unsure which ''OIG guidelines'' the commenter is referencing, we do confirm that nothing in the safe harbor exempts contracts between eligible entities and transportation vendors from complying with all applicable fraud and abuse laws for terms of an arrangement that are not protected by this safe harbor. For example, an eligible entity may not require an ambulance company to provide free or discounted transportation to its patients as a condition of receiving referrals.

Eligible Entity

We proposed that the safe harbor protect only transportation offered or provided by an ''eligible entity.'' We proposed to define ''eligible entity'' as any individual or entity, except individuals or entities (or family members or others acting on their behalf) that primarily supply health care items (including, but not limited to, durable medical equipment (DME) suppliers or pharmaceutical companies). We specifically solicited comments on excluding other entities that provide primarily services, such as laboratories or home health agencies, that we posited might be more likely to offer transportation in return for referrals, resulting in both steering and overutilization. We stated we were considering excluding home health care providers from safe harbor protection when they furnish free or discounted local transportation to their referral sources, but not excluding them from protection when they provide such transportation to sources that do not refer to home health care providers, such as pharmacies.

Comment: One commenter requested that we consider the competitive advantages/disadvantages to providers being able to provide free transportation (*e.g.,* physical therapy providers who do in-home versus office visits). Another commenter asked that physical therapists expressly be allowed to provide free transportation. Commenters suggested including health plans, coordinated care entities, clinically integrated networks, managed care organizations (MCOs), and risk-bearing entities as eligible entities, and urged that MA plans should be able to include transportation subsidies in their CMS bids. One commenter requested that pharmacies be included, to accommodate transportation to and from the pharmacy, and another asked that dialysis providers expressly be included.

Response: We proposed to exclude from the definition of eligible entities suppliers of items, and potentially certain groups of providers or suppliers [11] of services that might be more likely to offer transportation to their patients in exchange for referrals. Physical therapists and dialysis facilities provide services, and we did not propose to exclude them. Pharmacies, however, primarily provide items and thus would be excluded from the definition. Many types of entities that may not directly render health care services to patients, such as health plans, MA organizations, MCOs, accountable care organizations (ACOs),[12] clinically integrated networks, and charitable organizations are not among the entities excluded from the definition of eligible entity and thus are eligible to provide transportation. However, one condition of the safe harbor prohibits shifting the cost of the transportation onto, *inter alia,* Federal health care programs. Thus, for example, to the extent that a MA plan's inclusion of the transportation program in its bid would affect costs to Federal health care programs or affect reimbursement, then we decline to adopt the commenters' suggestion. With that said, we recognize that MA organizations are permitted to include transportation as a supplemental benefit to its enrollees when such transportation meets certain requirements. As we have explained in other places, safe harbors do not create liability for parties; they protect arrangements that would otherwise be prohibited by the anti-kickback statute. To the extent that MA organizations are transparently offering transportation as a supplemental benefit, as permitted under the MA program, this safe harbor would not be necessary to protect those arrangements. With respect to effects on competition, we do not believe that the safe harbor will unfairly affect competition among providers and suppliers and, in fact, may encourage competition and improve patient access to care if transportation assistance enables patients to access a wider range of providers and suppliers from which to receive care.

Comment: One commenter recommended not permitting any health care providers or suppliers to provide transportation services, unless the provider or supplier is willing to transport the patient to other providers or suppliers of similar services. The commenter believes the safe harbor should protect only transportation services that transport a beneficiary to the provider or supplier of his or her choice.

Response: We respectfully disagree with the commenter's proposal, to the extent that it would apply to a provider who offered transportation only to its own premises. First, we believe the fact that the patient is established with the provider or supplier of service implies that the patient has, in fact, chosen that provider or supplier. We discuss the limitations on constraining patient choice in the context of one eligible entity transporting the patient to another provider or supplier elsewhere in this final rule.

Comment: Some commenters disagreed with our proposal to partially or fully exclude home health agencies from the definition of eligible entities. These commenters suggested that home health agencies are a critical link for patients to get to necessary appointments—some of which could be to referral sources. One commenter suggested that allowing home health agencies to provide transportation to a primary care provider will help patients who did not have a primary care provider before requiring home health services. One commenter stated that home health agencies are tasked with providing comprehensive care, and

[10] *See* MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2013), Chapter 7, *available at http://www.medpac.gov/documents/reports/chapter-7-mandated-report-medicare-payment-for-ambulance-services-%28june-2013-report%29.pdf?sfvrsn=2.* In fact, the report notes that: ''[i[f there are concerns about the availability of transport to dialysis treatment, an approach other than using ambulance transport is needed. One possibility would involve dialysis facilities providing local transportation services to their patients'' and notes the necessity of a safe harbor to permit such transportation. *Id.* at 187.

[11] In this safe harbor, we use the term ''supplier'' as it is defined for purposes of Medicare. That is, ''a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.'' 42 CFR 400.202. We are excluding suppliers of items, but including most suppliers of services (*e.g.,* physicians), in the term ''eligible entity.''

[12] We note that the term ''ACO'' may be used differently in different sectors and programs to describe a variety of types of entities that consist of a collection of providers or suppliers working together to coordinate care. As explained elsewhere in this final rule, some ACOs participate in the MSSP or certain CMS demonstration programs or models that are subject to oversight and have waivers of certain fraud and abuse laws. Other entities called ''ACOs'' do not participate in the MSSP or CMS demonstration programs or models and may not be subject to the same safeguards.

providing transportation can help reduce hospital readmissions and help physicians comply with face-to-face requirements. A commenter stated that home health agencies also can help patients pick up prescriptions when caregivers are not available. One commenter suggested that home health agencies be required to develop and document eligibility criteria, which must be unrelated to referral source, supplier, or type of treatment. One commenter recommended allowing home health agencies to be eligible entities for certain circumstances, such as when a patient cannot transport himself or is exhibiting serious symptoms requiring transport to a doctor who already has been treating the patient. Another commenter agreed with the concept expressed in the Proposed Rule of excluding home health agencies from transporting patients to their referral sources. Similarly, another recommended a facts-and-circumstances analysis for home health agencies. One commenter suggested that excluding whole categories of providers and suppliers unfairly penalizes legitimate entities, and that the other requirements in the proposed safe harbor provide sufficient safeguards.

Response: For many of the reasons cited by commenters, we have concluded that home health agencies should not be excluded from the definition of ''eligible entity.'' Individuals who provide home health services already travel to the patient's home and have regular communication with both the patient and the patient's health care providers or practitioners. In addition, patients eligible for home health services may be particularly in need of transportation, which home health agencies may be in a unique position to provide. We are aware, however, that home health agencies have historically posed a heightened risk of program abuse, and take this opportunity to remind all eligible entities that, to be protected by this safe harbor, the provision of transportation must be for medically necessary services and comply with all other conditions of the safe harbor. Moreover, the fact that transportation is potentially protected by this safe harbor would never insulate it from scrutiny as part of an investigation. For example, we have investigated schemes in which home health agencies recruited beneficiaries and transported them to physician offices to obtain prescriptions and renewals of prescriptions for home health services that they did not need. The provision of transportation, in such an instance, would be considered as part of a scheme to submit false claims for unnecessary services.

Comment: One commenter supported excluding DME suppliers and pharmaceutical manufacturers for the reasons stated in the Proposed Rule. Another commenter recommended against excluding suppliers of items, but suggested imposing additional limitations on those suppliers to curtail fraud and abuse. One commenter opposed excluding pharmaceutical manufacturers, and provided examples of situations in which it argued pharmaceutical manufacturers should be permitted to provide local transportation (*e.g.,* when patients should be accompanied home after receiving an infused drug treatment). One commenter objected to excluding suppliers of items, calling it an unjustified bias. This commenter believed that these suppliers and manufacturers do not pose a heightened risk of steering and suggested that OIG did not adhere to guidelines for establishing safe harbors. Despite agreeing with concerns we expressed, another commenter disagreed with excluding particular types of entities, suggesting that other safeguards in the safe harbor should offer sufficient protection. This commenter requested that, if we do exclude certain types of entities, we clarify that entities that offer both items and services (*e.g.,* a hospital that also has laboratory or pharmacy) could transport its patients to receive those both the items and services.

Response: We agree with the commenters that support excluding suppliers of items from the definition of ''eligible entity.'' Unlike physicians, hospitals, or other providers and suppliers of services, suppliers of items generally do not play a role in ensuring that patients have access to other providers and suppliers. They certainly can play a role in assisting a patient obtain transportation by bringing the need to the attention of, for example, the patient's physician, practitioner, or hospital. We are finalizing a rule that excludes only suppliers of items from the definition of eligible entity; we are not excluding home health agencies or laboratories. We respectfully disagree with the suggestion that we did not take into account the factors set forth by Congress to consider when developing safe harbors. We continue to believe, as we stated in the Proposed Rule, that allowing individuals and entities that primarily supply health care items to offer transportation to patients presents a heightened risk of using such transportation to generate referrals, potentially in a way that increases costs for patients and Federal health care programs. Entities that sell items, such as pharmaceutical manufacturers, generally do not need to furnish transportation to their own location. Offers by a pharmaceutical manufacturer to transport patients to physicians who are the manufacturer's referral sources could influence that referral source's decision to prescribe one drug over another. For example, a physician might be influenced to prescribe an expensive branded infusion drug in preference to a less expensive drug, if the manufacturer of the more expensive drug offered transportation to the patients who received it so that they can get to their appointments with the physician. Such a program could both influence the physician to choose a particular item and increase costs to Federal health care programs—two factors cited by Congress to consider when developing safe harbors—without necessarily increasing quality or patient choice. With respect to entities that primarily provide services, but also provide items, we confirm the commenter's understanding. That is, an entity, such as a hospital, could offer transportation to its established patients to its own location for items or services provided by the entity (such as for obtaining items at the hospital's on-site pharmacy).

Established Patients

We proposed to require that the free or discounted local transportation services be available only to ''established patients.'' We proposed that a patient would be ''established'' once the patient had selected a provider or supplier and had attended an appointment with that provider or supplier. In contrast, we proposed not to protect transportation offered to new patients. We received a number of comments on this proposal and have decided to modify our interpretation of the term ''established'' as it is used in the safe harbor.

Comment: Though acknowledging and agreeing with our efforts to prevent eligible entities from using free or discounted local transportation as a recruiting tool, a number of commenters asked us to consider the impact of the established patient requirement on patients who have not seen a primary care doctor in years, including patients who are newly insured or FQHC patients. Several commenters recommended that we deem a patient to be ''established'' once the patient selects the provider and calls to schedule an appointment. These commenters urged that many newly insured patients may need help getting to their first appointment, and that in some cases,

the first appointment may be critical or urgent (*e.g.,* a mental health patient whose communication indicates a need for prompt treatment). Other commenters suggested that limiting transportation availability to established patients will deter patients from changing providers.

Response: We agree with the thrust of the comments. The purpose of limiting the local transportation offers to established patients is to offer flexibility to improve patient care while limiting the risk of the transportation being used as a recruiting tool, or to bring patients in for unnecessary services. Because the eligible entity is not permitted to market the transportation services, we believe that making transportation available to new patients who contact the provider or supplier on their own initiative is sufficiently low risk to warrant safe harbor protection. Thus, a patient can be ''established'' for purposes of this safe harbor after he or she selects and initiates contact with a provider or supplier to schedule an appointment. If a patient is unable to call a provider or supplier himself, or has otherwise given consent for a person (*e.g.,* a family member, a case manager, or a provider or supplier where the patient is attending an appointment) to schedule appointments for him, then a request for an appointment made on behalf of the patient is sufficient to meet this criterion. We reiterate that transportation cannot be used as a recruiting tool. Thus, we view a case manager (*i.e.,* someone coordinating a patient's care) reaching out to schedule an appointment and asking if transportation might be available as being entirely different than a provider or supplier reaching out to the patient (or to the patient's case manager) and asking to have a new patient come in, coupled with an offer of transportation. The former would be protected (if all other conditions of the safe harbor are met), and the latter would not be.

Comment: We received questions about the scope of an entity with which a patient might be ''established.'' One commenter inquired whether a patient became established after a visit with a practice, or only as to the particular provider or supplier the patient had seen. Another thought the preamble suggested that a patient could be ''established'' only with a practice, and suggested that the patient should be ''established'' within a health system or network of providers. Similarly, we received a question about whether a single visit to a hospital ''establishes'' the patient for all future visits. Commenters asked how the ''established patient'' requirement would work with integrated entities (*e.g.,* whether a patient would be ''established'' within a whole system). Another asked whether a patient would be established at one dialysis facility, or others under common ownership (*e.g.,* if the patient usually receives dialysis at one facility but needs to reschedule an appointment at a different local facility). A commenter suggested that the safe harbor should protect both new and established patients of FQHCs. One commenter expressed a concern about steering, such as if a hospital or large practice could choose to offer transportation only to their own ancillary practices.

Response: We understand the commenters' concerns and requests for clarity regarding the provider or supplier with whom a patient is established. We believe that some of these issues are resolved by our conclusion that a patient is ''established'' with any provider once an initial appointment is made. Thus when a patient makes an appointment (including a rescheduled appointment), an eligible entity may offer transportation regardless of whether the patient has received services from that eligible entity in the past. We recognize, however, that when and with whom a patient is an ''established patient'' remains pertinent with respect to the commenter's concern regarding steering. We also recognize that eligible entities that do not directly provide health care services (*e.g.,* health plans, ACOs, health systems, etc.) would not have ''established patients,'' because patients do not receive health care from them. Such entities always would be considered to be providing transportation to another provider or supplier, and the patient must be ''established'' with that other provider or supplier. An eligible entity that is a health care provider or supplier may make transportation to its own location available to its own established patients, without offering transportation to the patients of other providers. However, the safe harbor requires that the availability of transportation not be determined in a manner related to past or anticipated volume or value of Federal health care program business. So, if an eligible entity chooses to make transportation available for services provided by others, it must provide the transportation to the provider or supplier of the patient's choice, subject to restrictions that an eligible entity can impose that are unrelated to referrals, as discussed below. Thus, if a patient is being discharged from the hospital, and the hospital is willing to transport the patient to followup visits with a cardiologist, the hospital cannot make that offer contingent on the patient choosing a cardiologist affiliated with the hospital. We note, the eligible entity can have various limits on transportation policies. For example, the eligible entity might be willing to transport patients only within a 10-mile radius of its location, or willing to transport patients only to primary care providers, or only for visits included in a discharge plan. These types of limitations are acceptable and do not limit patient choice or steer to particular providers or suppliers.

We interpret the commenter's question about how the ''established patient'' requirement would work with integrated entities as asking whether a patient who is established with a particular physician practice, for example, is also established with respect to the entire integrated health care system of which that practice is a part. If so, then the system would be able to provide transportation limited to entities within the system. We understand that integrated entities, health systems, and others would prefer to transport patients only to their own affiliated locations. At this time, we are not protecting such limited transportation offers to individual patients. We will continue to monitor the changing landscape and could consider new or revised safe harbors in the future. We do note that shuttles protected under this safe harbor are not subject to the established patient requirement. Thus a health care system could offer a shuttle service to the public that made stops at its own facilities, but not at any health care facilities outside the system. We also note that an ACO or similar entity may assist its affiliates in providing transportation (*e.g.,* by having a fleet of vehicles available for the use of its affiliates in transporting their patients). In this situation, the transportation would be provided by the affiliates, who could limit the transportation offers to their own patients. However, the safe harbor requires that eligible entities (in this case, the affiliates) bear the cost of the transportation they provide. This could be done by, for example, having the affiliates pay to the ACO a fixed amount per mile or per trip for their transported patients. We decline to require any particular method of calculating these costs, as long as the method reasonably compensates the ACO for the transportation provided. We note that, alternatively, ACOs in the MSSP and certain CMS demonstration programs may use waivers of the fraud

and abuse laws to cover some transportation arrangements, provided all waiver conditions are met.

Comment: A number of commenters raised general concerns that the ''established patient'' requirement was unnecessary, too restrictive, burdensome, or an arbitrary limit to care. One commenter suggested it should apply only to physicians, and another stated it should not apply to home health agencies. Others advocated it might prevent new patients from seeking care, or from attending new appointments, including hospital registration. An additional commenter urged us to consider that the requirement will create barriers to entry in the health care system, especially with Medicaid expansion. Several commenters expressed a concern that it would be burdensome or impossible to screen patients to ensure that only established patients used a shuttle around a hospital or extended campus.

Response: We believe that the revised interpretation of ''established'' should address many of these concerns. Further, except for the limited exception for ACOs and other eligible entities that do not have patients of their own, we do not see any reason to exempt certain categories of providers and suppliers from the requirement to offer transportation only to established patients. By allowing transportation to be offered to patients after the patient has an appointment, we believe we have removed the barriers to transportation to new patients that commenters described. We also note, most Medicaid programs include coverage for some form of non-emergency transportation services, which further reduces the likelihood that the established patient requirement will result in significant barriers to entry in the Medicaid program. As discussed in greater detail below, when transportation is in the form of a shuttle service, the established patient requirement does not apply.

Comment: One commenter recommended we include family and friends of skilled nursing facility (SNF) patients, as we approved in OIG Advisory Opinion 09–01. The commenter suggests that such transportation facilitates SNF residents keeping community ties.

Response: This section of the safe harbor is intended to address transportation for patients to obtain medically necessary services. While transportation of family and friends can serve important patient interests, as we recognized in OIG Advisory Opinion 09–01, we do not believe that this section of the safe harbor is the place to address that concern in the context of SNF patients, or other patients who would benefit from visits from family and friends. We are separately protecting shuttle services under this safe harbor. Thus a SNF or other provider would be able to offer a shuttle on a set route that could accommodate friends and family of residents. For other arrangements that do not meet all requirements of the safe harbor, the SNF could seek an advisory opinion.

Comment: Commenters urged us to ensure that the safe harbor is available for post-acute patients. For example, one commenter asked whether a SNF could transport a patient to its facility after the patient selected the facility, but before signing the admission agreement. Another commenter asked us to confirm that hospitals could provide transportation to ensure that post-discharge followup care was received. Another commenter was concerned about patients who come to the Emergency Department (ED) by ambulance. The commenter asserted that, whether or not those patients are admitted, they may need a ride home.

Response: We believe that each of the examples provided above could be protected by the safe harbor. Our revised interpretation of ''established'' would permit the SNF to transport the patient to its facility, as long as the patient selected the facility first on his or her own initiative (or through the patient's representative), whether or not an actual agreement had been signed. However, transportation for marketing purposes, offered to a patient who has not yet selected the facility, would not be protected by the safe harbor. A hospital providing transportation to its discharged patients for followup care would be protected under either interpretation of ''established;'' if the patient was admitted to the hospital or received outpatient care there, then the patient was an established patient of the hospital. The Proposed Rule had proposed protecting, and we are finalizing a rule that will protect, transportation offered by one provider or supplier to convey patients to or from another provider or supplier (so long as other requirements are met). Likewise, the safe harbor could protect transporting a patient home from an ED visit: A patient who has received a service is an established patient, and transportation of such a patient could be protected by this safe harbor.

Comment: One commenter requested that we define ''new patient,'' while other commenters asked whether one visit was sufficient to be established with the provider or supplier. Another commenter asked whether providers must document that transported patients are ''established.'' Other commenters suggested that we establish an exception, or include fewer restrictions, for patients in MA plans because, the commenters assert, there is a lower risk of steering or overutilization in these plans.

Response: We believe we have addressed most of these comments through the revised interpretation of ''established'' patient. We confirm here that the safe harbor does not require documentation that the patients receiving transportation are established patients. However, maintaining documentation that demonstrates compliance with the safe harbor may be best practice.

Comment: Some commenters argued that the established patient requirement does not consider patients with emergent situations (*e.g.,* an ESRD patient who needs to go to a new facility for a vascular access problem, or a patient who just discovered potential HIV infection). Commenters suggested that the safe harbor allow for transportation to be provided to new patients with emergent conditions because other safeguards mitigate risk. Another commenter specifically requested an exception process to address situations where one provider must transport a patient to another provider to reduce the risk of an emergency department visit or a hospital admission.

Response: We believe that the safe harbor, as it is being finalized, is sufficient to cover emergent situations, including situations that would prevent a hospital visit. If a patient has an emergent condition, needs a service, and reaches out to a provider or supplier to schedule an appointment and expresses concern about his or her ability to get to that appointment, the provider or supplier can offer transportation. Using an example provided by commenters, if a patient is at an ESRD facility and needs to get to a vascular access clinic, but has no way to get there, the safe harbor would be available to protect transportation offered by either the ESRD facility or the vascular access clinic. First, because the patient is established with the ESRD facility, the ESRD facility could transport him to the vascular access clinic, provided all other conditions of the safe harbor are met. Second, the patient could call the vascular access clinic to make an appointment and ask if transportation is available (or a call could be made on the patient's behalf, at the request of the patient or the patient's representative). By reaching out and making the appointment, the patient would be established with the

clinic for purposes of being eligible for transportation.

Purpose of Transportation

We proposed and solicited comments on conditions related to the purpose of the transportation and the location to which a patient could be transported. Specifically, we proposed that protected transportation be for ''the purpose of obtaining medically necessary items or services,'' but we solicited comments on whether eligible entities also should be protected under the safe harbor if they provide free or discounted local transportation for other purposes that relate to the patient's health care (*e.g.,* to apply for government benefits, to obtain counseling or other social services, or to get to food banks or food stores). We proposed to allow an eligible entity to provide free or discounted local transportation services to the premises of another health care provider or supplier, as long as the eligible entity does not make the free or discounted local transportation available only to patients who were referred to it by particular health care providers or suppliers, and as long as the offer of transportation is not contingent on a patient's seeing particular providers or suppliers who may be referral sources for the eligible entity offering the transportation. We received several comments on these proposals.

Comment: Several commenters recommended that transportation be allowed for purposes that relate to health care, and that such concept be interpreted broadly. For example, commenters recommended allowing transportation for non-clinical, but health-related activities (*e.g.,* obtaining counseling or other social services, getting to food banks/stores, applying for government benefits). Another commenter recommended allowing transportation for other services if the purpose of the services support care coordination and adherence to the patient's plan of care. One commenter supported the provision of transportation services for a variety of purposes, including those that are non-clinical but reasonably relate to an individual's health care and would be beneficial to the patient (*e.g.,* a risk-bearing provider might offer transportation to an exercise program, mental health counselor, or healthy grocery store).

Response: We decline to extend safe harbor protection to transportation for purposes other than to obtain medically necessary items or services at this time. A transportation program offered by a provider or supplier inherently poses a risk both of inducing patients to get items or services that they might otherwise not have obtained and to get the services from that provider or supplier. In the case of transportation for medically necessary items or services, we think that risk is acceptable. However, we believe the risk is too high when the transportation for an individual (as opposed to a shuttle) is for non-health-related purposes.[13] First, whether the patient's destination is really health-related would be difficult to determine, *e.g.,* if it is a shopping center that includes, in addition to a food store, a movie theater and other retailers. Transportation for food shopping or other non-medical reasons also might be more frequent than transportation for medical appointments, which would give larger providers a significant competitive advantage over smaller entities or individual suppliers. Nevertheless, as described below, an eligible entity could operate a shuttle service that includes stops at locations that do not relate to a particular patient's medical care. In addition, we will continue to monitor new payment models and methods of coordinated care that increase quality and reduce costs, and we will consider whether permitting transportation to non-medical services that are part of coordinated care arrangements or are related to improving health care, would be appropriate in a future rulemaking.

Comment: One commenter noted that we proposed prohibiting eligible entities from making transportation available only to patients referred by particular providers or suppliers. This commenter recommended that we also prohibit eligible entities from discriminating based on insurance type (*e.g.,* limiting transportation to Medicare patients).

Response: As the commenter correctly observed, we proposed prohibiting limiting transportation offers to patients referred by particular providers or suppliers. We also proposed requiring that the availability of the free or discounted transportation be determined in a manner unrelated to the past or anticipated volume or value of Federal health care program business. If transportation were offered only to Federal health care program beneficiaries, then it would be unlikely to meet this latter requirement. If an eligible entity transported only Federal health care program beneficiaries to itself, or only transported Federal health care program beneficiaries to other providers or suppliers, it would appear that the availability of the transportation took into account the volume, as well as possibly the value, of Federal health care program business. However, an eligible entity could take into account an individual patient's need for transportation, even if this resulted in the transportation being disproportionately made available to elderly or low-income patients who are more likely to be Federal health care program beneficiaries. It would be necessary for the determination of transportation to be made on an individual basis, however, and not on the basis of insurance type. For example, a geriatric practice might provide transportation almost exclusively to Medicare beneficiaries where most of its practice is Medicare beneficiaries, so long as the practice does not discriminate based on insurance type. In other words, any non-Medicare patients of the practice must be eligible for transportation assistance on the same terms as the Medicare patients.

Comment: Some commenters suggested that allowing transportation from one provider to another is essential, and gave the example of a hospital transporting a patient to affiliated post-acute sites. Another commenter supported transportation from one provider to another, as long as the patient is established with one of the providers. According to one commenter, excluding transportation to referral sources would limit the availability of transportation, given how many organizations and providers are part of ''intertwined referral networks.'' Another commenter recommended that, if health systems, health plans, ACOs, or other integrated networks are permitted to be eligible entities, they should not be permitted to restrict transportation to providers or suppliers in their own networks. Another commenter suggested the opposite: That integrated care systems should not have to transport patients to non-network providers, and that such a requirement would discourage hospitals from offering transportation.

Response: We agree with commenters that allowing one eligible entity to transport patients to another provider or supplier is important. We intend to protect this transportation, as long as it meets all other requirements in the safe harbor. We wish to clarify that, if the patient is being transported to a different provider than the eligible entity that is providing the transportation, and the eligible entity providing the transportation is itself a provider or supplier of federally payable services, then there must be an

[13] We note, however, transportation for non-medical purposes would not violate the statute if it is not for the purpose of inducing individuals to obtain federally reimbursable items or services.

established patient relationship between the eligible entity providing the transportation and the patient being transported, as well as an established patient relationship between the patient and the provider to which the patient is being transported. For example, a hospital that has discharged a patient (and therefore has an established relationship with the patient) may provide transportation for the patient to an appointment with a physician for followup care. In these circumstances, the hospital has an interest in ensuring that the patient is seen for followup care, in order to avoid complications and possible readmission. The hospital may not, however, offer to transport a patient with whom it has no established relationship (either as an inpatient or outpatient) either to the hospital's own facilities or to the facilities of a different provider or supplier. If a provider with no established relationship with a patient provides or offers to provide transportation,[14] there is a risk that a purpose of the transportation is to market its own services to the patient or induce referrals from the provider to whom the patient is being transported. As explained above, an eligible entity that does not itself provide health care services (such as a charitable organization, health plan, ACO, or other entity) is not required to have an established relationship with a patient in order to provide transportation that is protected by this safe harbor.

We did not propose to exclude transportation to referral sources, other than potentially in the context of entities that we were considering fully or partially excluding from the definition of ''eligible entity'' (*e.g.,* our proposal to exclude home health providers from providing transportation to their referral sources). Under the Proposed Rule, and as we are finalizing in this final rule, an eligible entity can transport patients to another provider or supplier that is a referral source; the transportation offer, however, cannot be contingent on the patient choosing a referral source. For example, a hospital could offer transportation services to its established patient diagnosed with cancer who needs to see an oncologist. The hospital would need to provide transportation to any oncologist that the patient chooses (subject to the hospital's policy on distance), not only to the oncologists who are referral sources for the hospital. This restriction holds true in networks. For example, if a hospital will transport a patient to a clinical laboratory, radiology provider, or specialist, the patient must have the freedom to choose the provider or supplier; the hospital cannot make the offer of transportation contingent on the patient using a clinical laboratory, radiology provider, or specialist in its network. The hospital can, however, set restrictions on the distance it is willing to transport the patient.

Comment: One commenter disagreed with our proposal to exclude from safe harbor protection free or discounted local transportation that an eligible entity makes available only to patients who were referred to the eligible entity by certain providers or suppliers. The commenter recommended allowing an eligible entity to limit transportation only to patients from particular providers in the context of ACOs in the MSSP. The commenter notes that ACOs participating in the MSSP do not benefit from increased referrals or overutilization, because the goal of that program is to improve quality while lowering Medicare cost growth. The commenter suggested that this condition should not apply to MSSP ACOs because such ACOs are designed to reduce spending, not increase it. Thus, increased referrals should not be a concern.

Response: We are not adopting the commenter's suggestion. CMS administers the MSSP pursuant to section 1899 of the Act. In addition, CMS operates a number of models pursuant to its authority under section 1115A of the Act. The MSSP and some of the models operated pursuant to section 1115A of the Act have waivers of certain fraud and abuse laws, including the anti-kickback statute. Parties involved in the MSSP or models under 1115A authority may not need this safe harbor to provide transportation, if they meet all the conditions set forth in an applicable waiver for the program in which they are participating.

Need for Transportation

In the Proposed Rule, we sought comments on whether we should require eligible entities to maintain documented beneficiary eligibility criteria. After consideration, we are finalizing a requirement that eligible entities have a set policy regarding the availability of transportation assistance, and must apply that policy uniformly and consistently. However, eligible entities are not required to maintain individualized documentation for each patient to whom transportation is provided. While not required to be protected under the safe harbor, maintaining such documentation would be a best practice to demonstrate compliance with the requirements of the policy and the consistent and uniform application.

Comment: Some commenters maintained that providers should not be required to have established criteria that patients must meet to qualify for transportation. One commenter suggested it would be intrusive and would discourage patients from seeking transportation. One commenter suggested transportation should be available to all patients, plus family members and friends who are involved in a patient's care. Others agreed that it is acceptable, appropriate, or even crucial to require providers to have policies regarding financial or transportation need. One commenter supported community-based need criteria, rather than individual need. Another commenter believed that the criteria should be based on the availability of and access to transportation, or to a driver willing to transport the patient. Another agreed with requiring the provider to maintain criteria, but urged OIG to avoid burdensome requirements or extensive documentation (*e.g.,* a provider should be allowed to use Medicaid as a proxy for showing financial need). This commenter also recommended allowing different ways to show need (*e.g.,* risk of missing treatment, certain medications making them unable to drive). One commenter stated that eligible entities should be able to set caps on the amount of transportation provided (*e.g.,* an annual cap on the use of transportation services).

Response: As stated above, we have determined that eligible entities must maintain a consistent policy for offering free or discounted transportation. We decline to mandate the parameters for this policy, other than the fact that it must comply with other terms of this safe harbor (including distance, and the prohibition on transporting only to referral sources), and must be applied uniformly and consistently. For example, one practice might have a policy to ask any patient who schedules any procedure that inhibits the patient's ability to drive himself or herself home whether that patient needs local transportation assistance. Another practice might offer local transportation assistance to any patient who has a history of missing appointments. Other providers or suppliers might have specific need criteria. Another provider might have a policy of never offering transportation unless the patient specifically states that he or she cannot get to an appointment due to a lack of transportation. We believe that the other

[14] We note that the considerations are different, as explained below, in the context of a shuttle service.

requirements in this safe harbor should protect Federal health care programs and beneficiaries, and that eligible entities should have the flexibility to develop policies to suit their patient populations' needs within those requirements. However, certain eligibility criteria would not be appropriate. For example, we do not agree that a patient's status as a Medicaid (or Medicare) beneficiary should be used as a proxy for establishing transportation need, in part because this would result in transportation being offered on the basis of volume or value of Federal health care program business. If the eligible entity has a need-based policy, the fact that a patient is a Medicaid (or Medicare) beneficiary does not establish that he or she has a need for transportation; nor does the fact that a patient is not a Medicaid (or Medicare) beneficiary establish a lack of transportation need. For example, a Medicaid beneficiary may have ready access to affordable public transportation, while a patient with more financial resources may not. While eligible entities are free to tailor their transportation programs to the needs of their own patient populations and communities (including setting caps on available transportation), they may not do so in a way that is linked to status as a Federal health care program beneficiary.

Comment: Several commenters stated that requiring eligibility documentation or a screening process for each patient would be burdensome and would cause delays in the availability of transport. Some commenters cited privacy concerns. Others stated that documentation requirements will deter providers from offering the transportation. Others agree with documentation of need, with one commenter suggesting it is necessary for OIG oversight. One commenter suggested that patient need should be established by patient self-declaration, but that such need should be noted in the patient record or discharge plan. Another supported ''reasonable'' documentation of need.

Response: As we explain above, an eligible entity offering transportation must do so consistently and uniformly, in accordance with its own policy. If an entity believes that an inquiry as to transportation need raises privacy concerns, the entity is free to offer transportation without regard to need, as long as it does so consistently. We agree with commenters that documenting need for each patient could be burdensome, particularly for eligible entities that have a more generous transportation assistance program. We are not requiring entities to document transportation assistance provided, if it is in compliance with the eligible entity's policy (but again, we suggest it might be best practice to do so).

Modes of Transportation

We proposed to limit the form of permissible transportation by excluding air, luxury, and ambulance-level transportation from safe harbor protection. Commenters generally agreed with this proposal.

Comment: Several commenters generally agreed with our proposals to exclude air, luxury and ambulance-level transportation. One commenter agreed with excluding those types of transportation, but recommended that we consider patient needs (*e.g.,* some patients may be capable of riding a bus, while others might need a taxi). Some commenters requested clarification that the safe harbor extends to third-party public transport. One commenter noted that excluding air transport is limiting for patients who must travel long distances for quality care, while another commenter suggested we should protect air travel if that is the usual mode of transportation in the area. Another commenter suggested that unadvertised ambulance transport should be available when no other option is available. Some commenters requested that chair cars be permitted.

Response: We are finalizing our original proposal. We agree that transportation in vehicles equipped for wheelchairs (other than ambulances) and third-party transportation, including public transportation, would be protected if it meets the other criteria of the safe harbor. While there may be individual cases (or communities) that justify air or ambulance-level transportation, those situations would need to be considered on a case-by-case basis. We recommend that providers or suppliers seeking to use alternate forms of transportation request an advisory opinion.

Comment: One commenter generally supported the proposal to permit a shuttle service but suggested that few, if any, restrictions be placed on hospital shuttle service transportation offered in the 30-day post-discharge or 7-day post-ED-visit timeframes.

Response: We recognize the importance of post-discharge care for patients. While the commenter used the term ''shuttle service,'' transportation geared to post-discharge care is less likely to be in the form of a shuttle and more likely to be offered to the patient on an individualized basis. As described in detail below, we are separately protecting shuttle services, and those services are subject to fewer restrictions than transportation offered to a particular patient on an individualized basis.

Comment: Several commenters expressed a concern that it would be burdensome or impossible to screen patients to ensure that only established patients used a shuttle around a hospital or extended campus.

Response: In this final rule, we expressly state that eligible entities offering a shuttle service would not be required to limit the service to established patients.

Marketing

We proposed several conditions related to marketing in connection with offering free or discounted local transportation. We proposed that the transportation assistance could not be publicly advertised or marketed to patients or others who are potential referral sources, that no marketing of health care items or services could occur during the course of the transportation, and that drivers or others involved in arranging the transportation could not be paid on a per-beneficiary-transported basis. We are finalizing these proposals, with certain clarifications.

Comment: Commenters noted that signage on vehicles is important for safety. One commenter suggested that vehicles should be allowed to include signs and pamphlets about services to be received.

Response: As we stated in the Proposed Rule, we agree that signage designating the source of the transportation on vehicles used to transport patients (or shuttles available to non-patients) is an important safety feature and would not be ''marketing,'' for purposes of the safe harbor. However, we respectfully disagree that providers should be able to post signs or give patients pamphlets or other marketing or informational materials during transport. Any discussion of services that patients may receive should come from the health care provider or supplier, not the transportation provider. Information about other services that the provider or supplier might offer is precisely the type of marketing this restriction strives to prevent. We are willing to protect transportation that helps patients get the care they need; we are not willing to protect transportation that is used as a sales tool.

Comment: One commenter recommended that MA organizations or other risk-bearing entities be allowed to

advertise publicly the availability of transportation. The commenter states that such advertisements would reduce costs, and may be the only way to get the information to low-income populations.

Response: Individuals or entities seeking to avail themselves of this safe harbor may not advertise the availability of the transportation. However, as explained above, we do not believe that all transportation offered by organizations such as a MA organization would require the protection of this safe harbor (*e.g.,* when the transportation is being provided as a supplemental benefit). Every entity would need to evaluate the terms of a transportation program, on a case-by-case basis to determine whether the statute is implicated. If it is not, safe harbor protection would be unnecessary.

Comment: Several commenters requested that we clarify that providers are permitted to distribute information to patients who may need transportation but would not otherwise know it is available. Commenters variously suggested, for example, that providers be able to offer transportation proactively to patients who might need it, or permit statements that transportation is available subject to certain conditions. One commenter inquired whether information could be on the provider's Web site or in printed materials. Another suggested the requirement should be sufficiently flexible to allow patients to learn about opportunities for transportation.

Response: We agree with commenters that informing patients that transportation is available is not marketing, if it is done in a targeted manner. For example, if a patient learns that he or she needs to come to a followup appointment, or is scheduling a procedure that might require a safe ride home, it would be permissible to ask if the patient has a reliable mode of transportation. However, providers and suppliers should not advertise the availability of free or discounted transportation (including on Web sites or in printed materials distributed to the public). As we explain below, this rule is slightly different for shuttle services.

Comment: One commenter agreed that a provider or supplier could pay drivers or others involved in arranging the transportation on a mileage or other fixed-rate basis, but not per-beneficiary-transported. Another requested that the safe harbor permit providers or suppliers to offer nominal public transportation fees (*e.g.,* bus fare) to individual patients. Another commenter advocated that we permit providers and suppliers to reimburse patients directly, through vouchers, or through cash reimbursement.

Response: We agree with the commenters' suggestions, which largely support our proposals. If transportation is offered via a driver or private company hired by the eligible entity, that eligible entity cannot pay the driver or person/entity involved in arranging for the transportation on a per-patient-transported basis (although it could pay on the basis of total distance traveled by a vehicle). However, if transportation is provided in the form of nonprivate transportation (such as taxi or bus), the transportation would be paid for or reimbursed to individual patients through, for example, taxi vouchers or bus fare, or cash reimbursement if the patient has a receipt to show that he or she incurred the cost of the transportation.

Comment: One commenter requested clarification as to whether acknowledging donors constitutes marketing (*e.g.,* a sign in the vehicle saying ''donated by ABC Chevrolet'').

Response: In the Proposed Rule, we proposed prohibiting the marketing of health care items and services. We are finalizing this proposal. If a donor is a health care provider or supplier, or makes, markets, or sells health care items or supplies, an acknowledgment of that donor's contribution would be prohibited. If the donor is not a health care provider or supplier, or does not sell or provide health care items or supplies, the acknowledgement would not violate that condition of the safe harbor.

''Local'' Transportation

As we explained in the preamble to the Proposed Rule, this safe harbor is intended to protect ''local'' transportation. We proposed that if the distance that the patient would be transported is no more than 25 miles, then the transportation would be deemed to be ''local.'' We solicited comments on whether 25 miles is an appropriate distance, whether 25 miles should be a fixed limitation rather than a distance ''deemed'' to comply with the safe harbor, and other reasonable methods for interpreting the term ''local.'' In response to comments, and as described in more detail below, we have decided to have separate distance limits for rural areas and urban areas. We defined ''rural area'' as an area that is not an ''urban area,'' as defined in this rule. We defined ''urban area'' as: (a) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or (b) the following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. These definitions are intended to be consistent with the physician self-referral law definitions of the same terms.

Comment: Some commenters proposed specific distances that are farther than 25 miles. Proposals included 35 miles, 50 miles, and 100 miles. Some of these commenters proposed allowing the transportation at least within this expanded distance or to the closest facility capable of providing the necessary care. Many commenters recommended considering a greater distance than 25 miles for providers and suppliers in rural or underserved areas, where patients travel much greater distances to access appropriate care. Commenters noted that CAHs must be at least 35 miles away from the nearest hospital or other CAH. Certain commenters suggested that providers serving rural or medically underserved communities should be exempt from any mileage limits. One commenter gave this example: In a rural area, a patient might go to a hospital for an outpatient procedure that could be done in an office; if the office is farther away than the hospital but transportation is allowed, the patient could receive care in a less expensive setting.

Response: This final regulation maintains the proposed 25-mile distance for patients in an urban area but expands the definition of ''local'' to 50 miles for patients in a rural area, as defined in this rule. The mileage can be measured directly (*i.e.,* ''as the crow flies''), which would include any route within that radius (even if such route is more than 25 or 50 miles when driven).

We arrived at our determinations of 25 and 50 miles after considering input from commenters and additional consultation with our government partners. We reviewed the United States Department of Agriculture (USDA) Economic Research Service's (ERS) data on Frontier and Remote (FAR) ZIP code areas, developed using data from the 2010 census. In an article describing these FAR levels (of which there are four), ERS explained that ''[h]ealth care access is the primary policy issue motivating this research.'' [15] FAR level

[15] John Cromartie, David Nulph, and Gary Hart, *Mapping Frontier and Remote Areas in the U.S.,*

Continued

one includes ZIP codes in which the majority of the population lives 60 minutes or more from an urban area [16] of 50,000 or more people. FAR level four breaks down the travel time to other areas: not only are the majority of those residents 60 minutes or more from urban areas with 50,000 or more people, they are 45 minutes or more from urban areas of 25,000–49,000 people, 30 minutes or more from urban areas of 10,000–24,999 people, and 15 minutes or more from urban areas of 2,500–9,999 people. According to the article, 6.5 percent of the U.S. population is classified as FAR level one, while 1.7 percent is classified as FAR level four (and thus, 93.5 percent of the population would not be classified as FAR). We note, MSAs contain at least one urbanized area of 50,000 or more people. In conjunction with this data, we reviewed a Working Paper titled ''Geographic Access to Health Care for Rural Medicare Beneficiaries'' that presented research and data on how far rural patients had to travel to access health care.[17] This paper included both median distance in miles and median time in minutes and presented the data in different categories: Selected diagnoses (*e.g.,* dementia, congestive heart failure, fractures, malignant neoplasms) and procedures (*e.g.,* intubation for emergency, cardiac surgery, radiation oncology, general medical exam, dialysis). All diagnoses presented showed a median distance under 50 miles. Only two procedures showed a median distance over 50 miles, and those were for patients considered ''isolated rural,'' defined in this paper as ''in or associated with a rural town of fewer than 2,500.'' We believe that expanding the distance to 50 miles for patients in rural areas should protect transportation that meets the vast majority of patients' needs, while still being ''local'' for their communities.

We believe that a 25-mile distance should be sufficient for patients in urban areas to access quality health care, and can be fairly characterized as ''local.'' We recognize that there may be areas within urban areas, as we are definining that term in this regulation, that are generally underserved, or underserved as to particular types of health care services. However, we believe using definitions of ''rural area'' and ''urban area'' in this safe harbor that are consistent with definitions of the same terms used in connection with the physician self-referral law at 42 CFR 411.351 and 412.62(f)(1)(ii) will be simplest for providers to work with and encourage the widest use of this safe harbor.

Individuals and entities anticipating a need to transport over longer distances and believing that they have sufficient safeguards in place to avoid abusive outcomes, such as steering of patients and inducements to obtain unnecessary care, may seek an advisory opinion for a determination on whether the program is sufficiently low risk.

We are sensitive to the fact that patients living in rural areas may have fewer health care providers and suppliers in their immediate areas, and that transportation might provide these patients with more choices and better access to quality care. We note that the requirement for a longer distance is that the patient resides in a rural area. Thus, the eligible entity (or the provider or supplier to whom the patient is transported) may or may not be in a rural area.

We believe that other suggestions provided by commenters are not appropriate for a safe harbor. For example, eliminating any kind of mileage or other limit would not give providers any kind of certainty as to whether they were offering ''local'' transportation, as required by the safe harbor. We also do not believe that a requirement that transportation be to the closest facility capable of providing treatment is appropriate. There is likely to be uncertainty as to whether any facilities were closer to the patient, whether those facilities provide the needed service, whether such service is available within the time needed by the patient, and the like. We believe the two mileage limits that we are finalizing are sufficient to help patients access care while giving eligible entities a definite test to apply to determine whether their transportation assistance meets the ''local'' requirement of the safe harbor.

Comment: Several commenters proposed allowing a hospital or other provider to transport patients to the nearest facility capable of providing medically necessary items or service. Some commenters specifically cited specialized care (such as radiation oncology) or a specific facility type (*e.g.,* for IHS beneficiaries, Indian tribe, tribal organization, or urban Indian organization health facility), which could be farther than 25 miles away. Some commenters proposed including the nearest facility as an alternate (*i.e.,* 25 miles *or* to the nearest provider or supplier who can provide the care).

Response: As explained above, we have retained our proposed 25-mile limit for patients in an urban area, but have modified our original proposal to protect transportation up to 50 miles for patients located in rural areas. As we also explain above, a condition that limits transportation to the nearest provider or supplier could unnecessarily limit patient choice, and application of such a standard could create a burden for patients or providers.

Comment: Certain commenters expressed a concern that a 25-mile limit could impede clinically integrated systems that span a greater distance from providing transportation among facilities in their systems.

Response: The purpose of this safe harbor is to protect free or discounted local transportation. We do not consider distances greater than 25 miles to be ''local'' in urban areas, or 50 miles in rural areas, for purposes of this safe harbor. We understand that there may be beneficial, low-risk transportation arrangements that the mileage limit will exclude from protection under the safe harbor. Entities desiring to implement an arrangement that implicates the statute and does not meet the terms of the safe harbor may submit an advisory opinion request so that we can determine, on a case-by-case basis, whether the arrangement is sufficiently low risk to be protected.

Comment: We received comments with a range of reasons to eliminate any fixed mileage limit. Commenters suggested that providers are in the best position to develop mileage criteria that reflect local characteristics; the distance is irrelevant, but transportation should be allowed only in certain circumstances (*e.g.,* severe weather); any time or distance limit is arbitrary, prescriptive, or too stringent; and any time or distance could be appropriate, depending on the facts and circumstances. Some commenters proposed using the provider's primary service area, or using longer distances for rural or medically underserved areas.

Response: While we understand that a set mileage limit is not a one-size-fits-all solution, we believe that a bright-line rule is easier for all parties to apply. Eligible entities will benefit from having the confidence that their arrangements fit within the safe harbor. We discuss our rationale for not implementing certain alternatives proposed by commenters elsewhere in this rule.

Amber Waves, Dec. 2012, Vol. 10, Issue 4, available at: *http://www.ers.usda.gov/media/960626/datafeature.pdf.*

[16] The cited research uses the term ''urban area'' as described in this preamble, which is not necessarily the same as ''urban area'' as defined in the final regulation.

[17] Leighton Chan, MD, MPH, L. Gary Hart, Ph.D., David C. Goodman, MD, *Geographic Access to Health Care for Rural Medicare Beneficiaries* (WWAMI Rural Health Research Center, Working Paper #97, April 2005).

Comment: A number of commenters supported an approach referenced in the Proposed Rule of permitting transportation offered to patients within the primary service area of the provider or supplier (or other location) to which the patient would be transported. One of these commenters suggested defining ''primary service area'' as any jurisdiction from which the provider or supplier receives at least 10 percent of its patients. Some commenters noted that time or distance measurements vary too much in different areas (*e.g.,* it could take an hour to travel 25 miles through an urban area, but only 20 minutes to cover the same distance in a rural area). Likewise, argued a commenter, most of a provider's patients might be within a 25-mile radius in an urban area, but that same radius might include less than half of a provider's patients in a rural area.

Response: We considered this approach, but we maintain that using a mileage limit is more appropriate. We agree that time and distance measurements, and providers, suppliers, and patients within those time or distance limits, vary by region. However, we believe that by using a set mileage limit, which now includes the original 25-mile proposal as well as a 50-mile distance for patients in rural areas, we are balancing the need for patients to get local transportation for services, and the certainty that comes with a bright-line rule.

Comment: Certain commenters support the 25-mile limit as a ''deeming'' provision. In other words, 25 miles would always be acceptable, but greater distances would be permissible under appropriate circumstances (*e.g.,* a rural or specialized facility that is farther than 25 miles away).

Response: While we have adopted fixed mileage limits for the reasons specified above, rather than the deeming concept that we proposed in the Proposed Rule, we did expand the distance to 50 miles for patients in rural areas. Again, these distance limits preserve the concept of ''local'' transportation, while accommodating transportation needs greater than our original proposal of 25 miles for patients in rural areas. We may consider other types of transportation arrangements in future rulemaking.

Comment: One commenter does not believe ''rural'' or ''underserved'' should be defined, both because the commenter claims that federal definitions of ''rural'' fail to address communities' unique barriers, and because ''local'' should include the service line's service area.

Response: We are relying on a definition of ''rural'' for the rule that includes anything outside of an urban area, which is consistent with the definition of ''rural area,'' as defined in the physician self-referral law.

Prohibition on Cost-Shifting

We proposed that the eligible entity bear the costs of the free or discounted local transportation services, and not shift the burden of these costs to Medicare, a State health care program, other payers, or individuals. Many commenters supported this requirement, but some asked for specific clarifications.

Comment: One commenter asked that we clarify that transportation offerors cannot shift costs to third-party vendors (*e.g.,* ambulance providers). One commenter recommended that transportation offerors be required to report incurred costs on cost reports to CMS.

Response: We do not believe it is feasible or necessary to require specifically in this final rule that transportation offerors not shift costs onto third-party transportation vendors. First, we believe that our proposed prohibition on shifting costs and requiring the transportation offeror to bear costs itself covers the commenter's concern. Moreover, this safe harbor protects only the offering, giving, soliciting, and receiving of the transportation. It does not protect behind-the-scenes arrangements to implement the transportation. Thus, if a hospital were to shift the costs of its transportation program to an ambulance provider under an explicit or implicit threat of withholding future referrals, such activity could still violate the anti-kickback statute and would not be protected under this safe harbor. Whether transportation costs should be reported on cost reports is outside the scope of this rulemaking; however, any reporting of the cost of transportation that would serve to shift such costs to Federal health care programs would take the transportation out of the protection of this safe harbor.

Comment: One commenter suggested that providers should be permitted to enter into cost-sharing arrangements with local or state entities, or with nonprofit organizations or charities. This commenter believes providers should not be required to bear the ''full'' costs. Another commenter noted that smaller practices should be able to pool resources to offer transportation.

Response: We agree that providers and suppliers should not have to bear the full cost of transportation, if they can get donations or contributions from appropriate sources. However, in the absence of an agreement among entities to share costs, entered into voluntarily and without any tie to referrals, the costs should not be shifted to any payer, individual, or other provider or supplier. This prohibition is not intended to bar entities from voluntarily joining together to offer transportation. Investing in transportation is not necessarily different than making any other investment (and donating transportation is not different than making any other donation). For example, a charity might donate a vehicle to a hospital, or a health system or an ACO might purchase vehicles that would be available for use by its providers or suppliers (at their cost pursuant to the safe harbor requirement that the eligible entity bear the costs of the transporation) to transport their patients (*i.e.,* the ACO or health system would not be acting as the eligible entity; the transporting provider or supplier would be). Any agreement parties enter into to make this investment would not be covered under this safe harbor (which protects the transportation itself), but it also would not disqualify the transportation from the protection of this safe harbor, as long as the terms of the agreement would not result in transportation that fails to meet the conditions of the safe harbor (*e.g.,* if the agreement involved tying the availability of transportation to referrals). Parties would need to ensure that the agreement does not violate the anti-kickback statute or other fraud and abuse laws.

Shuttle Transportation

We sought comments on whether we should separately protect a second form of transportation akin to a shuttle service. We received a number of comments about offering a shuttle service, and which of our proposed safe harbor criteria should, or should not, apply to that form of transportation. In short, this final rule separately protects a shuttle service under the safe harbor. Some safeguards will be the same, and others will be different, compared to the more personalized form of transportation contemplated by this safe harbor. First, we interpret the term ''shuttle'' to be a vehicle (not air, luxury, or ambulance) that runs on a set route, on a set schedule. Second, the ''established patient'' requirement will not apply to shuttle services. Third, we are not mandating where the shuttle can or cannot make stops, other than continuing to require that the shuttle transportation be local. Because we anticipate that shuttle routes may include multiple stops, ''local'' would mean that there are no more than 25 miles between any stop on the route and any stop at a location where health care

items or services are provided, when measured directly. If any stop is in a rural area, the distance would be up to 50 miles from that stop. Thus, if a health system runs a shuttle that stops at a hospital, a public transportation stop (the only stop in a rural area), a grocery store, and a clinic, all stops other than the public transportation stop must be within 25 miles of the hospital and the clinic (if measured directly, without regard for intervening stops), and the hospital and the clinic must be within 50 miles of the transportation stop in the rural area. Fourth, the marketing prohibitions apply to shuttle services, except that the schedule and stops can be posted. The rest of the requirements of the safe harbor (*e.g.,* eligible entity requirements, other marketing, and the prohibition on cost-shifting) all apply to shuttle services. We summarize the comments received below and provide additional details.

Comment: A number of commenters expressly agreed with our proposal to allow shuttles, and others implicitly agreed by commenting on other requirements (such as the established patient requirement) in the context of a provider running a shuttle. One commenter requested that we clarify that providers and suppliers can contract with third parties to run shuttles. Another commenter requested protection of a shuttle, bus, or van route that includes neighborhoods served by a hospital, public transportation stops, and the hospital campus or other hospital campuses. One commenter urged us to require that a shuttle must transport patients to providers other than those affiliated with the eligible entity running the shuttle.

Response: We agree that shuttle vans or buses should be permitted under this safe harbor, and that some different safeguards should apply. We offer the following responses to specific comments. (1) We would not mandate who runs the shuttles (whether it is the eligible entity or a contractor of the eligible entity operating the shuttle service). (2) For various reasons, we are not requiring that the shuttle be limited to established patients. Unlike door-to-door transportation in which a driver is sent to pick up a specific patient, a shuttle would run on a regular route. We believe it would be burdensome if we required shuttle drivers to determine whether individuals using the shuttle were established patients of one of the facilities where the shuttle would stop. Also, a shuttle service may be used for reasons other than to obtain healthcare items or services, or to obtain such items or services from a particular provider, practitioner, or supplier. For example, we expect many shuttles would be available to employees of the eligible entity or visitors to one of the eligible entity's facilities as well as to patients. If the entity furnishing the shuttle service chooses also to make it available to the general public, we do not believe that this would materially increase the potential for abuse. Other safeguards (*e.g.,* restrictions on marketing) limit the risk that the shuttle would be used to recruit new patients. Should an eligible entity prefer to limit shuttle services to established patients, such a limitation would not be prohibited under this safe harbor. However, it is not a requirement. (3) We decline to adopt the recommendation that the shuttle be required to stop at providers unaffiliated with the provider or supplier offering the shuttle service. We are also not approving (or disapproving) particular types of stops as appropriate for a shuttle service. We believe that such requirements would be unworkable in a safe harbor. For example, if a hospital in an urban area offered a shuttle in roughly a 10-mile radius around the hospital, there could be dozens, if not hundreds, of unaffiliated providers, practitioners, or suppliers on or near that route, as well as a variety of stops that are included primarily as patient pick-up locations. We believe the eligible entity offering the transportation is in the best position to determine the types of shuttle stops that are appropriate for the applicable community and that the safeguards included in the final rule are sufficient to mitigate risks associated with offering shuttle transportation.

C. Civil Monetary Penalty Authorities: Beneficiary Inducements CMP

When reviewing comment summaries and responses below, it is important to remember what the beneficiary inducements CMP prohibits, in contrast to certain other fraud and abuse laws, such as the anti-kickback statute. First, the beneficiary inducements CMP prohibits inducements only to Medicare and State health care program [18] beneficiaries. Second, it prohibits inducements to those beneficiaries only if the offeror knows or should know the inducement is likely to influence the beneficiary to receive a reimbursable service from a particular provider, practitioner, or supplier. Unlike the anti-kickback statute, which prohibits offering or giving remuneration to induce beneficiaries to order an item or service, the beneficiary inducements CMP is triggered if the person providing the remuneration knows or should know that it is likely to induce the beneficiary to order the item or service from a particular provider, practitioner, or supplier. For example, if a hospital were to offer a beneficiary remuneration post-discharge to follow up with a physician (without regard to who that physician might be, and without recommending a particular physician or group), the beneficiary inducements CMP would not be triggered and no exception would be necessary. In contrast, an entity like a pharmaceutical manufacturer, which is not a provider, practitioner, or supplier, could nonetheless implicate the statute if it offered or gave remuneration to a beneficiary that it believed would be likely to induce the beneficiary to order an item or service from a particular provider, practitioner, or supplier (*e.g.,* to choose a particular physician or pharmacy). With that background, the following section summarizes the comments we received on each of the exceptions proposed in the Proposed Rule.

1. Copayment Reductions for Outpatient Department Services

We proposed to incorporate the statutory exception set forth at section 1128A(i)(6)(E), which permits hospitals to give reductions in copayment amounts for certain outpatient department (OPD) services. The statutory cite to the definition of ''covered OPD services'' was outdated, so we proposed to use the current statutory reference. We received no comments on this proposal, and we are finalizing it, as proposed.

2. Promotes Access/Low Risk of Harm

Section 1128A(i)(6)(F) of the Act includes an exception that protects ''any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations).''

We note that other exceptions to the beneficiary inducements CMP, and some safe harbors to the anti-kickback statute (which are incorporated by reference as exceptions to the beneficiary inducements CMP), may cover activities or arrangements that arguably ''promote access to care and pose a low risk of harm to patients and Federal health care programs.'' This exception should be read in the context of those more specific exceptions and safe harbors: We would look to other applicable exceptions to consider whether the remuneration in question

[18] All references to ''State health care program'' in this final rule rely on the definition of that term found at section 1128(h) of the Act.

poses a low risk of harm. Thus, activities and arrangements that are addressed by another beneficiary inducements CMP exception or a safe harbor and meet the elements of the applicable safe harbor or exception would be considered to be low risk under this exception. For example, one type of remuneration cited by numerous commenters that could promote access to care is free transportation. We have set out conditions in the anti-kickback statute safe harbor for local transportation that we believe are necessary for such transportation to be ''low risk.'' If a local transportation arrangement did not meet the requirements of the safe harbor (*e.g.,* it would be long-distance transportation, or transportation that is advertised), it would be unlikely to be low risk under this exception. However, we recognize that each arrangement should be subject to an analysis of the facts and circumstances. For example, if a transportation arrangement did not meet all conditions of the safe harbor, but had different safeguards in place, it could be low risk under this exception. We note, however, that this exception does not apply to the anti-kickback statute. Entities desiring to enter into transportation arrangements that do not meet the requirements of the anti-kickback safe harbor may wish to seek an advisory opinion.

For activities and arrangements that are not addressed by a more specific safe harbor or exception, anyone asserting this exception as a defense will have the burden of presenting sufficient facts and analysis for OIG to determine that the arrangement promoted access to care and posed no more than a low risk of harm to patients and the Federal health care programs, as described in this Final Rule.

In the Proposed Rule, we proposed certain interpretations of the statutory language to inform our development of regulatory text. We also solicited comments on a number of specific aspects of the statutory language. The responsive comments fall into three general categories: (1) What constitutes ''care;'' (2) what it means to ''promote access'' to care; and (3) what type of remuneration poses a low risk of harm to patients and Federal health care programs. We also received questions about types of programs or arrangements that might meet the exception, or other general questions. We address these comments in turn, and we intend to strictly interpret the language of this exception, as described in detail below.

a. Promotes Access to Care

The Term ''Care''

In the Proposed Rule, we characterized ''care'' as ''medically necessary health care items and services.'' 79 FR 59717, 59725 (Oct. 3, 2014). We also solicited comments on whether we should interpret ''care'' more broadly to include nonclinical care that is reasonably related to medical care, such as social services. *Id.*

Comment: Some commenters supported protecting remuneration that promotes access to nonclinical care that is reasonably expected to affect the patient's health (*e.g.,* dietary counseling, social services). One commenter suggested that we should broaden our interpretation to include nonclinical care and protect any activity related to care that is encouraged through CMS's Medicare Star Ratings system. Another commenter recommended that the exception should include access to nonclinical services reasonably related to treating, managing, or preventing a condition identified in a published recommendation of the U.S. Preventive Services Task Force. Another commenter suggested that promoting access to nonclinical care fosters efficiency and quality improvement goals of integrated care arrangements.

Response: At a high level, we agree with the commenters who suggest that certain types of nonclinical items and services can improve overall health and help meet quality-improvement goals. However, after considering comments that expressly addressed this question, in combination with how this term affects other aspects of the exception, we do not agree that the term ''care'' in this exception should be expanded beyond items and services that are payable by Medicare or a State health care program. For clarity, because some State health care programs (such as Medicaid) cover some services that are not strictly medical (such as personal care services for beneficiaries who are unable to care for themselves), we are revising the standard to encompass items and services that are payable by Medicare or a State health care program, rather than by reference to medical necessity. Thus, when we refer to ''care'' in the context of ''access to care'' throughout the following discussion, we mean access to items and services that are payable by Medicare or a State health care program for the beneficiaries who receive them.

In response to the comment regarding the Medicare Star Ratings system, we note that the activities encouraged under this system include many types of care, such as health screenings, vaccines, and managing chronic conditions. If the remuneration promotes access to care, and is low risk, it would be protected. The exception applies to a prohibition on remuneration that is likely to influence a beneficiary to order or receive items or services from a particular provider, practitioner, or supplier for which payment may be made by Medicare or Medicaid. As explained above, we believe it therefore follows that the ''care'' alluded to in the exception is care provided by the particular provider, practitioner, or supplier, which is payable by Medicare or a State health care program. As further noted above, we are defining the term ''access to care'' as access to items or services payable by Medicare or a State health care program. We decline to define ''care'' more broadly because the statutory exception provides no guidance as to what constitutes ''care,'' beyond that which is covered by these programs, or what other kinds of care should be included. Notwithstanding our conclusion on this point, we will continue to monitor the changing payment and health care delivery landscape for possible future exceptions. In addition, we emphasize that individuals and entities can still help and encourage beneficiaries to access nonpayable care without implicating the beneficiary inducements CMP. For example, individuals and entities can provide patients with objective information (such as educational materials or other resources) about community resources. Moreover, when items or services are not reimbursable by Medicare or State health care programs, the statute would be triggered only if the offeror of the remuneration knew or should have known that the remuneration was likely to influence a Medicare or State health care program beneficiary to receive reimbursable services from a particular provider, practitioner, or supplier. For example, a MA organization or a Part D plan could provide remuneration to its enrollees to help them access nonpayable care, without implicating the beneficiary inducements CMP; MA organizations and Part D plans are not providers, practitioners, or suppliers, and under ordinary circumstances remuneration from them to access nonpayable items or services would not be likely to induce a beneficiary to use a particular provider, practitioner, or supplier for an item or service payable by Medicare. Likewise, an employee in a physician's office could work with Medicare or State health care program patients to refer them to resources in

their communities (*e.g.,* for assistance with housing, food, or domestic violence counseling). Providing these educational or informational services to patients would not implicate the beneficiary inducements CMP.

Comment: Commenters requested that the exception protect remuneration in the form of the provision of nonclinical items that improve medical care or are reasonably related to medical care. Among the nonclinical items commenters suggested should be permitted are health and wellness-related technology hardware and software, computer and smartphone applications, home monitoring devices, telemedicine capability, nutritional services (*i.e.,* meals or meal preparation services), health and wellness coaching, mental or physical activity initiatives, social services, legal services, Internet classes, language instruction, and discount programs that tie health and wellness achievements to the receipt of retail items and services.

Response: We note that the question of whether the form of remuneration can be a payable item or service is a different question from the ''care'' to which access is promoted by the remuneration. A number of commenters provided suggestions of beneficial items or services (*i.e.,* forms of remuneration) that are nonpayable by Medicare or State health care programs. It is possible that any of the examples of remuneration above would not violate the CMP under appropriate circumstances. If the provision of an item or service is not likely to influence a beneficiary to choose a particular provider, practitioner, or supplier, it does not implicate the statute. The provision of remuneration that does implicate the statute could be protected by this or another exception, if all conditions of the exception are met. In evaluating a particular arrangement for the provision of remuneration to beneficiaries under this exception, we would consider whether the arrangement promotes access to care (*i.e.,* items or services payable by Medicare or a State health care program) and is a low risk of harm to patients and Federal health care programs, in accordance with the guidelines set forth here.

Comment: Some commenters disagreed with limiting the exception to access to care in the form of items and services that are medically necessary. One commenter suggested that tying access to care to ''medically necessary items and services'' would exclude items or services given before seeing a doctor, because the provider would not necessarily know what services the beneficiary would require or whether such services are medically necessary. Two commenters suggested that the standard would be burdensome for health plans, pharmacy benefit managers, and OIG because it would require patient-specific reviews by individuals with medical expertise, and would exclude items that are ''reasonably related'' to medical care.

Response: We did not propose limiting the exception to remuneration that is medically necessary; the remuneration must increase the beneficiary's ability to obtain care and pose a low risk of harm. We do not believe the restriction we proposed would exclude items or services given before seeing a doctor. Remuneration may come from any individual or entity to facilitate a beneficiary's obtaining care, as defined herein, from a provider, practitioner, or supplier for the first time. For example, if a patient makes an appointment with a physician practice, the practice may send the patient a monitoring device (such as a blood pressure cuff, heart rate monitor, or purchase code for a smartphone app) to collect health data before the appointment. As we explain above, we revised our interpretation of ''care'' from medically necessary items or services to items or services payable by Medicare or a State health care program. We do not believe it would be burdensome for health plans or others to be familiar with the types of items or services that are payable by these programs. Further, as we explain in greater detail below, we believe programs can be developed at the beneficiary-population level for greater efficiency. With that said, we would not protect remuneration that would be likely to influence a patient to access unnecessary care from a particular provider, practitioner, or supplier. As a separate matter, as we explain above, the remuneration itself does not need to be payable items or services; the remuneration must promote access to such care.

Comment: One commenter suggested that restricting the exception to remuneration that promotes access to medically necessary care conflicts with the suggestion that the remuneration could promote access to nonclinical care and is not required by statute.

Response: We agree that we could not adopt both standards. The standard that we are adopting protects remuneration that promotes access to care (items and services that are payable by Medicare or a State health care program); we solicited comments on whether our proposal should be expanded to apply to remuneration that promotes access to nonclinical care (and poses a low risk of harm). For purposes of this exception, we believe a necessary safeguard to protect both patients and Federal health care programs is to limit the scope of the exception to remuneration that promotes access to items and services that are payable by Medicare or a State health care program. As we note elsewhere, we will continue to monitor the changing health care delivery and payment landscape, as well as changing understandings of the relationship between traditional health care services and non-traditional services that improve health, and consider whether additional or revised exceptions are necessary in the future.

The Term ''Promotes Access''

We proposed that the exception would include only remuneration that ''improves a particular beneficiary's ability to obtain medically necessary items and services.'' We solicited comments on multiple aspects of this proposal. We asked whether we should interpret ''promotes access'' more broadly, to include encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient than it otherwise would be. As we explain in greater detail below, many of the comments that we received proposing a broader interpretation sought protection for remuneration that could fit within our original proposal. After considering all of the comments, we decline to adopt a broader interpretation of ''promotes access'' than we proposed (subject to our revised definition of ''care''), but we note that items or services that support or help patients to access care, or make access to care more convenient than it otherwise would be often would meet our original proposed interpretation. We also asked whether the remuneration would have to promote access to a particular beneficiary or whether it should also apply to a defined beneficiary population. We have determined that the exception should apply to remuneration that promotes access either to a particular individual or to a defined beneficiary population.

Comment: Some commenters supported protecting remuneration (including what some commenters characterized as programs to offer remuneration) to promote access to care for a particular beneficiary population, as well as individual beneficiaries. One rationale offered to expand the protection to remuneration that promotes access to care for a beneficiary population is to facilitate use of the exception operationally; the commenter suggested that lines can be blurred between what is offered on an

individual basis versus what is offered to a defined group. One commenter noted that a broader interpretation of the individual(s) for whom a program might promote access to care allows for the development of innovative programs. One commenter supported population-specific programs for free or discounted services, such as participation in smoking cessation, nutritional counseling, or disease-specific support groups.

Response: We agree with the commenters that the exception should apply to remuneration that promotes access to care for a defined beneficiary population, and not be limited to remuneration offered on an individual patient-by-patient basis. With that said, the form of remuneration does not matter (as long as it is an item or service, and not cash or a cash equivalent, and not a copayment waiver), and could include participation in smoking cessation, nutritional counseling, or disease specific support groups, but the remuneration would have to comply with the other prongs of the exception: It must promote access to items or services that are payable by Medicare or a State health care program (and pose a low risk of harm to patients and Federal health care programs). Such an analysis would depend on the facts and circumstances. For example, a primary care group practice might purchase and make available to its diabetic patients a subscription to a Web-based food and activity tracker that includes information about healthy lifestyles. Depending on the cost of this subscription, it could constitute remuneration to the patient. This remuneration would promote access to care because it would help the patient understand and manage the interaction between lifestyle, disease, and prescribed treatment and would create a record that would facilitate interactions with the physician for future care-planning. In other words, the service is a tool that patients would use to access care and treatment because it helps them access improved future care-planning by their physican. In contrast, an ophthalmologist could not offer a general purpose $20 debit card to every patient who selected him as a surgeon to perform cataract surgery because the debit card does not help the patient access care, and remuneration that is cash or a cash equivalent [19] is not low risk.

Comment: We received numerous comments generally supporting the concept of broadly interpreting the definition of ''promotes access to care'' to encompass encouraging patients to access care, supporting or helping patients to access care, or making access to care more convenient for patients than it otherwise would be. Commenters suggested that the broader definition is justified, in light of the shift toward coordinated or integrated care that depends on patient engagement. Commenters further suggested that a more narrow definition could exclude many types of beneficiary incentives that would help patients to access care. Another commenter expressed concern with a broad definition, and recommended that OIG adopt a standard for medical necessity similar to the one Medicare uses and clarify how it would be enforced. Commenters suggested specific examples of types of remuneration that should fit into the definition of ''promotes access'' to care, such as transportation, self-monitoring tools, post-discharge contacts, and incentives to be proactive for health care needs.

Response: We believe that interpreting ''promotes access to care'' as improving a particular beneficiary's [or, as noted above, a defined beneficiary population's] ability to obtain items and services payable by Medicare or a State health care program is sufficiently broad. We appreciate the commenters' desire for a broad definition of ''promotes access,'' and upon review of the comments, we have determined that some of the phrasing about which we solicited comments (*e.g.,* ''helping patients to access care'' or ''making access to care more convenient'') could be included in the concept of improving a beneficiary's ability to access care. We recognize that there are socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan. Our interpretation of items or services that ''promote access to care'' encompasses giving patients the tools they need to remove those barriers. As we discuss below, this interpretation would not, however, incorporate the concept of rewarding patients for accessing care; the exception protects items or services that should improve a patient's ability to access care and treatment, not inducements to seek care. Thus, some suggestions from commenters would not fit into our definition. Incentives to be proactive for health care needs might not improve a beneficiary's ''ability'' to access care (though we note, the preventive care exception [20] does protect incentives to seek preventive care). For example, if a patient had a health condition for which a smoking-cessation program was a payable service, under this exception, a provider could offer free child care to the patient so that the patient could attend the program, but the provider could not give the patient movie tickets or any other reward for attending a session or series of sessions. A patient might not be able to attend the appointment without child care assistance, but the movie tickets do not improve the patient's ability to attend the appointment. Other examples provided by commenters could fit in the exception, under appropriate circumstances. Transportation assistance was a common request from commenters. If a provider, practitioner, or supplier offered local transportation or parking reimbursement to patients for appointments for items or services payable by Medicare or a State health care program, such remuneration would improve a beneficiary's ability to access that care.[21] Self-monitoring tools also could promote access to care. For example, a hospital might send a patient home with an inexpensive device to record data, such as weight or blood pressure, that could be transmitted to the hospital or the patient's physician. This remuneration could increase the beneficiary's ability to capture information necessary for followup care and to comply with the treatment plan. Post-discharge contacts limited to communications with the patient ordinarily would not constitute remuneration and thus would not require the protection of an exception to the CMP.

We also believe that the definition we are finalizing is broad enough to facilitate coordinated or integrated care. A goal of coordinated care is to improve the delivery of medically necessary care (and eliminate medically unnecessary care). If remuneration associated with a coordinated care arrangement meets the requirement of being low risk and helps the patient to access necessary care, the remuneration could fit in this exception.

[19] OIG considers ''cash equivalents'' to be items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card, but not a gift card that can be redeemed only at certain stores or for a certain purpose, like a gasoline gift card).

[20] The ''preventive care exception'' is a statutory exception at section 1128A(i)(6)(D), and an exception to the definition of ''remuneration'' at 42 CFR 1003.110.

[21] Note, however, that the remuneration must also be low risk. In this final rule, we have included a safe harbor to the anti-kickback statute that protects local transportation that meets certain requirements. As noted above, any remuneration that meets the requirements of a safe harbor is also excepted from the beneficiary inducements CMP. The safeguards set forth in that safe harbor would help ensure that the remuneration is low risk.

We recognize that the exception does not include inducements to seek care. However, we note that items of nominal value do not require an exception. *See* Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002 (2002 Special Advisory Bulletin), available at: *http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.* In the 2002 Special Advisory Bulletin, we stated our interpretation that the CMP permits inexpensive gifts (other than cash or cash equivalents) of no more than $10 in value individually or $50 in value in the aggregate annually per patient. Concurrently with the issuance of this final rule, we are announcing an increase in these limits, based on inflation, to $15 for an individual gift and $75 in value in the aggregate annually per patient. We are mindful that some CMS models permit incentives to seek care through waivers of the beneficiary inducement CMP. At the present time, methods used in these models are being tested to learn what might improve quality and patient outcomes without increasing costs. We will continue to monitor the results of such programs and will consider whether new or expanded exceptions are warranted in the future.

Comment: One commenter suggested that the definition of ''promotes access to care'' should require compliance with a particular treatment plan, and prohibit suggestions of specific providers and suppliers.

Response: We respectfully disagree with both suggestions. First, the commenter seems to imply that the exception is available only after the patient has an established care plan. However, the exception also would protect remuneration that promotes access in the first instance, and thus no treatment plan would exist. With respect to the second suggestion, if there is no likelihood of influencing a beneficiary to use a specific provider or supplier, the statutory prohibition would not be triggered, and complying with an exception would not be necessary.

Compliance With a Treatment Plan

As we explain in responses to the various comments below, rewards for accessing care, including compliance with a treatment plan, do not ''promote access'' to care. However, remuneration that helps a patient comply with a treatment plan (*i.e.,* removes an impediment or otherwise facilitates compliance with a treatment plan) could promote access to care. The following comments and responses address these issues.

Comment: Several commenters recommended that the definition of ''promotes access'' should permit remuneration that promotes compliance with a treatment plan, or programs that promote adherence to medication therapy (in contrast to the previous comment, which suggested that a treatment plan should be required as a condition of any remuneration permitted by this exception). One such commenter said that, if permitted, the remuneration to promote compliance with a treatment plan must be part of a written followup plan.

Response: We agree that some forms of remuneration that remove impediments to compliance with a treatment plan could constitute promoting access to care and could fit within the exception (as long as the remuneration also is low risk, as explained below). Items that are mere rewards for receiving care, as opposed to items or services that facilitate access to that care, would not meet the definition of ''promotes access'' to care. For example, remuneration in the form of an item that dispenses medications at a certain time for a patient could meet the exception because it is a tool that enables the patient to access the right drugs at the appropriate dosage and time. Reimbursing parking expenses or providing free child care during appointments also could promote access to care and help a patient comply with a treatment regimen. In contrast, offering movie tickets to a patient whenever the patient attends an appointment would not fit in the exception; such remuneration would be a reward for receiving care and does not help the patient access care, or remove a barrier that would prevent the patient from accessing care. We do not intend to require that remuneration that removes an obstacle to a patient's ability to comply with a treatment plan be part of a written followup plan because we do not believe that remuneration with this purpose should be different than any other remuneration permitted under the exception. In other words, if remuneration promotes access to care—whether the patient is at the beginning of the course of care or is in the middle of a treatment plan—and is low risk as described below, the remuneration can meet the exception.

Comment: We received a number of comments addressing our stated concern that rewards offered by providers or suppliers to patients purportedly for compliance with a treatment regimen pose a risk of abuse. Some commenters supported allowing remuneration that encourages patient participation and compliance. One commenter specifically requested that the exception include pharmacy programs that promote compliance with medication regimens. Some commenters suggested that allowing targeted incentives would promote adherence and reduce utilization of high-cost services and support similar goals articulated in the ACA. Another commenter recommended that we avoid imposing specific safeguards, as long as the incentives do not steer patients to a particular provider or supplier. Some commenters note that incentive programs are effective in particular settings (*e.g.,* the Alaska Native and American Indian community and in medication adherence programs). One commenter noted that similar programs, using incentives of nominal value, have been effective. Other commenters proposed specific safeguards, discussed further below.

Response: As we address above, we have determined that inducements to comply with treatment or rewards for compliance with treatment do not ''promote access to care'' and thus are not protected by this exception. We note however, that some of the comments above relate to activities that might not trigger liability under the statute. For example, if an incentive would not be likely to influence a patient to use a particular provider, practitioner, or supplier, the incentive would not implicate the beneficiary inducements CMP. Likewise, if the remuneration is of nominal value, it would not implicate the statute (again, because items and services with a low retail value are unlikely to influence the beneficiary to choose a particular provider, practitioner, or supplier). If an individual or entity desires to offer a program that it believes would be beneficial but might implicate the beneficiary inducements CMP, the advisory opinion process remains available.

Comment: Some commenters submitted examples of remuneration that they believed should be allowed as incentives to comply with a treatment regimen. One commenter suggested that incentives such as computer/smartphone apps, gift cards, and fitness trackers would encourage compliance and that similar rewards were approved in advisory opinions, citing OIG Advisory Opinion Nos. 12–14 and 12–21. One commenter gave an example of a lottery: Only patients who are in compliance with a treatment regimen may enter, and then even fewer will win (though the payout could be significant). Commenters offered a variety of examples of incentives or rewards that they believed should be protected under

the exception, such as: Rewards for routine exercise, gifts by health plans to incentivize enrollees to obtain preventive services or achieve benchmarks for controlling chronic conditions, discount programs that tie health and wellness achievements to the receipt of retail items and services, or rewards for positive outcomes (such as smoking cessation, losing weight). Another commenter requested that we specify that the exception covers rewards for actual access to care, not just promoting access to care.

Response: We believe many of the examples offered could meet the exception, but we respectfully disagree with the commenter that suggests that the exception covers rewards for accessing care as opposed to promoting access to care. For example, smartphone apps or low-cost fitness trackers could, depending on the circumstances, promote access to care; they could be used to track milestones and report back to the treating physician. Gift cards that relate to promoting access to care (*e.g.,* a gift card specifically for an item that would monitor the patient's health) could potentially fit into the exception as well. However, the examples structured as rewards (*e.g.,* rewards for routine exercise) would not be covered. Similarly, it is unlikely that a lottery or raffle system that rewards compliance would promote access to care, as we interpret the term.[22] We will continue to monitor patient engagement incentives as they develop in the industry, including new CMS models, and may propose future rulemaking as results become known. We again note that no exception is necessary if remuneration offered to patients is not likely to induce the patient to select a particular provider, practitioner, or supplier, including items and services of nominal value, and that incentives to seek preventive care could be covered under the preventive care exception.

In responding to various aspects of the Proposed Rule, some commenters asked about health plans providing incentives to their members to seek preventive health services, or to achieve certain health-related benchmarks. If health plans (or other entities that are not providers, practitioners, or suppliers) offer these incentives to seek particular services without influencing members to use particular providers or suppliers, the beneficiary inducements CMP is not implicated. If the incentives would influence members to use a particular provider or supplier, then the same conditions and interpretations of this exception would apply to health plans that apply to providers, practitioners and suppliers. However, all individuals and entities remain subject to the anti-kickback statute, and remuneration not prohibited under the CMP could be prohibited under the anti-kickback statute. For example, if a pharmaceutical manufacturer offered rewards or incentives for treatment compliance (without regard to any provider or supplier furnishing treatment), it might not implicate the beneficiary inducements CMP because the rewards would not incentivize the beneficiary to receive items or services from a particular provider or supplier, but it would implicate the anti-kickback statute because the remuneration could induce the beneficiary to purchase a federally reimbursable item.

Comment: Several commenters addressed the question of whether risk-bearing providers should be able to provide incentives for compliance with a treatment regimen. One commenter recommended that fee-for-service providers and suppliers should be allowed to provide remuneration to incentivize compliance, as certain ACO entities can. Another commenter recommended that providers taking on financial risk, such as some providers in ACOs, should be able to offer incentives. One commenter recommended that providers in fee-for-service alternative models (such as full or partial capitated models, ACOs outside of MSSP, medical homes, and others) be allowed to offer any kind of incentive (including cash equivalents) because the providers are rewarded on the basis of results rather than volume, and because patients are often assigned to providers (so the incentive wouldn't influence choice of provider).

Response: We believe that all individuals and entities seeking to rely on this exception should be required to meet the same standards. We agree that the incentives are different with risk-bearing providers and suppliers and ACOs than they are with traditional fee-for-service providers and suppliers. However, those characteristics should make it easier for those entities to meet the standards of the exception. If they are accountable for cost and quality, it is more likely (but not guaranteed) that the remuneration would be low risk. We do not believe that they should be exempted from the standards by virtue of their organization as an ACO or risk-bearing provider, nor should they be permitted, by virtue of this exception, to provide incentives that do not promote access to care. Once again, however, we note that if the incentive would not influence the beneficiary to receive services from a particular provider, practitioner, or supplier, then it would not implicate the statute. In addition, if the incentive were to encourage a beneficiary to access preventive care, that remuneration could be protected under the preventive care exception.

Comment: Several commenters addressed the question of whether certain safeguards should apply to incentives given for compliance with a treatment regimen. One commenter disagreed with safeguards, especially dollar limits, on incentives for compliance with treatment regimens. The commenter said some entities cannot track dollar limits for coupons. Another commenter recommended a $500 per beneficiary limit. One commenter proposed no dollar limit if the incentive is linked to health and wellness and has a reasonable connection to medical care, or a $100 limit if the item is not so linked. Another commenter generally suggested that the dollar amount should not be disproportionate to the patient's benefit from treatment. Another commenter suggested that dollar limits are arbitrary: An inexpensive app or device might be helpful for one patient, while another patient might need legal services or social services to get housing. One commenter recommended that the incentive should have a reasonable relationship with the treatment regimen. Commenters proposed a host of other safeguards for remuneration to incentivize or reward compliance with a treatment regimen. Some recommendations relate to documentation requirements (*e.g.,* milestones reached, evidence of past noncompliance). Other commenters recommended that the incentives themselves must be related to care management. One commenter suggested that we require offerors to submit plans to CMS to evaluate effectiveness; if not shown to increase compliance, it would not be protected. Other commenters recommended against particular safeguards. For example, one commenter did not believe that the form of an incentive should be limited, or that the incentive itself should have to relate to medical care. Another commenter recommended against quality or performance metrics. Another generally requested guidance on how the exception would protect incentives

[22] A raffle, however, could be of nominal value and not implicate the statute. For example, if the prize would be worth $100, and there were 20 participants with an equal chance to win that prize, we would consider each chance to be worth only $5. Although the winner would receive the prize worth $100, that patient had only a 1 in 20 chance of winning it, so the chance was worth only $5. If lottery tickets are available for purchase by the public (*e.g.,* a state lottery), however, we would consider the value be the purchase price.

to engage in wellness or treatment regimens.

Response: Because we are not permitting incentives or rewards for compliance with a treatment regimen under this exception, some of the comments regarding incentives related to medically necessary care or treatment are moot. However, to the extent that some of the suggestions could apply to remuneration or programs that could fit within the exception, we address them in turn. First, we do not propose to include a specific dollar limit on remuneration to deem it ''low risk.'' We agree with the commenter that noted that a very low value item might be appropriate for one patient, while the cost of an item or service that promotes access to care for a different patient could be more expensive. We also do not believe it is appropriate to require any kind of plan to be submitted to CMS, or to require any kind of reporting to qualify for the exception. Because the exception applies only to remuneration that promotes access to care (*i.e.,* increases a beneficiary's ability to obtain items or services payable by Medicare or Medicaid), we assume the items or services, if obtained by the beneficiary, would be reflected in the beneficiary's medical record (whether remuneration was provided to the patient or not). We include further discussion about the form of remuneration below.

b. The Term ''Low Risk of Harm''

We proposed that for remuneration to be a ''low risk of harm to Medicare and Medicaid beneficiaries and Medicare and Medicaid programs,'' the remuneration must: (1) Be unlikely to interfere with, or skew, clinical decision making; (2) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient-safety or quality-of-care concerns. We received general support from commenters regarding our approach to defining what it means to be a ''low risk of harm'' to patients and Federal health care programs. We also received a number of more specific comments and requests for clarification, which we detail below.

Comment: One commenter believed that strict controls were unnecessary for pharmacy programs for various reasons. First, the commenter noted that pharmacies ordinarily cannot dispense a prescription drug to a beneficiary unless a prescriber has determined that the drug is medically necessary and issued a prescription order, thus reducing the risk of unnecessary orders. The commenter further asserted that the risk of a pharmacy program increasing costs is also low in the pharmacy context because pharmacy programs that promote medication adherence result in lower overall healthcare costs, and most pharmacy reimbursement rates are established by prescription drug plans (PDPs), MA plans and Medicaid Managed care plans, or are capped by Federal and State reimbursement limits. Finally, the commenter asserted that patient safety and quality of care issues are much less of a concern in the pharmacy context, because the Food and Drug Administration (FDA) ensures that medications dispensed by pharmacies satisfy stringent quality control requirements.

Response: We respectfully disagree that pharmacy programs should be subject to any fewer safeguards than other programs. Pharmacies are no less likely to try to induce beneficiaries to use their services (over the services of another pharmacy) than other providers or suppliers, and they also may encourage overutilization by unnecessarily refilling prescriptions or inappropriate utilization by encouraging switching to more expensive drugs. Controls on reimbursement and FDA requirements might place some limits on medically unnecessary services, but we remain concerned about quality of care and inappropriate utilization leading to increased costs.

Comment: One commenter was concerned that the second element (regarding increasing costs) might be too narrow with respect to Part D and requested that costs should be viewed in the context of the totality of the patient's care.

Response: We understand the commenter's point and agree with its general premise. If a program promotes access to care, then care is more likely to be obtained. Therefore, some costs will increase, while others may decrease. For example, if a patient is discharged from the hospital with a prescription to manage newly diagnosed diabetes, cost to the Part D program might increase because of the new prescription, but overall health care costs may decrease because the patient will be managing a condition with the drug rather than having a higher chance of being rehospitalized. Thus, we agree that the harm to be avoided is an overall increase in health care costs. However, the condition we proposed was not that the remuneration be unlikely to increase costs at all, but that it be unlikely to increase costs through overutilization or inappropriate utilization. Incentives to access a higher level of care than necessary, or to use a higher cost brand name drug instead of a lower cost generic drug would not be low risk.

Comment: Some commenters generally agreed that valuable gifts in connection with direct or indirect marketing are not low risk. One commenter requested bright-line guidance regarding the distinction between educational activities and marketing. The commenter suggested that ''educational programs'' focusing on the skills or qualities of particular providers should be excluded from protection under this exception, but that nonmarketing, *bona fide* educational materials should not considered marketing simply because they included a logo of a provider.

Response: As we discuss in various guidance documents, such as the 2002 Special Advisory Bulletin, we agree that remuneration given in connection with marketing is not low risk and therefore would not be protected under this exception. Such remuneration is, almost by definition, given for the purpose of influencing the choice of a particular provider, practitioner, or supplier, and may induce overutilization or inappropriate utilization. However, we do not consider educational materials alone (even educational materials that include information about the qualifications of a particular provider) to be remuneration. Thus, a provider or supplier may offer educational materials (such as written materials about disease states or treatments), or informational programs (such as a program to help patients with asthma or diabetes learn more about controlling their diseases) to patients or prospective patients without implicating the beneficiary inducement CMP. However, if a provider, supplier, or other entity offered patients attending such a program an item or service (of more than nominal value), that the offeror knows or should know is likely to influence the patient to choose that provider or supplier, such remuneration would not be protected under this exception.

c. Other Examples and Comments

Comment: We received a number of comments providing examples of items or services that commenters believed should be protected by the exception. One type of remuneration could be categorized as health-care-related services. A sampling of remuneration that commenters suggested that we protect includes free- or reduced-cost health screenings (*e.g.,* blood pressure or fall-risk screenings); charitable dental care; education programs (*e.g.,* regarding diabetes or nutrition); post-discharge support; family support services; chronic condition management; education about insurance or medical leave benefits; lodging provided by a

hospital the night before procedures; transportation to appointments; other services that help patients live within their own communities; discounts for copayments; and gift cards for ongoing medications. Some commenters recommended that screenings should not be conditioned on obtaining other services from the provider or supplier and should not be selectively offered (*e.g.,* based on insurance type).

Response: We agree with the commenters' suggestions that free or reduced-cost health care screenings and services and discounts for drugs promote access to care and may be low risk. However some forms of remuneration (including cash or cash equivalents) would not be low risk, as we have indicated in previous guidance, such as the 2002 Special Advisory Bulletin. In addition, copayment waivers generally are not low risk. We note, however, that copayment waivers that meet certain conditions are separately protected under section 1128A(i)(6)(A) of the Act and 42 CFR 1003.110 and 42 CFR 1001.952(k). We also agree with comments suggesting that providing education or information about medical leave or insurance benefits would promote access to care and be low risk (and we believe that education or information alone would not qualify as ''remuneration'' at all.) Lodging before a procedure, or transportation to appointments, also could be protected under appropriate circumstances.[23] The local transportation safe harbor to the anti-kickback statute included in this rulemaking sets forth a number of factors that, taken together, would render transportation low risk. It would be prudent to structure any free or reduced-cost transportation arrangements to comply with the safe harbor because transportation to obtain Federal health care program-covered items and services generally will implicate the anti-kickback statute. We note that many forms of free or reduced-cost services (*e.g.,* free screenings at a health fair or charitable dental program, post-discharge support, chronic care management) could lead the patient to seek followup care with the provider or supplier that offered the free service.[24] Assuming the free screenings or health care services are not simply marketing ploys but rather identify or assist with necessary care, they could fit in the exception and be protected. Individuals and entities seeking to offer any of the listed items or services must determine, as an initial matter, whether they promote access to care (and if so, whether they are also low risk). For example, ''family support services'' could promote access to care (*e.g.,* if they are in the form of child care offered during an appointment), but that term also could be more broad and include services that are not directly related to the patient accessing care. The same is true for ''services that help patients live within their communities.'' Services such as transportation could be protected; services unrelated to helping the patient access care would not be.

Comment: Commenters suggested a wide variety of tangible items that the commenters believe should be protected, such as health- or wellness-related technology (*e.g.,* apps, or other items that would help patients record and report health data); discounted over-the-counter medication or medical supplies; free or discounted access to food services (*e.g.,* Meals on Wheels); educational materials; food vouchers; mattress covers; vacuum cleaners; scales; air conditioners; medical devices (such as blood pressure cuffs); programmable tools that help with medication dosage, refill reminders, medical appointment reminders, or dietary suggestions; home monitoring devices; telemedicine capability; free or discounted glucose meters; incentives for scheduling (*e.g.,* a dialysis facility giving an incentive to a retired patient to move his dialysis appointment earlier in the day so that a working patient can have an evening spot); and items that help manage clinical outcomes. Other commenters suggested that some items might not be low risk, such as a smartphone with a health data app. One commenter would like us to require a comparison of cost versus utility of the device for medical care.

Response: Many of these commenters' suggestions promote access to care, or remove obstacles to compliance with treatment regimens (*e.g.,* free or discounted medications, supplies, or devices; technology for reporting health data; scales; or programmable tools to help with medication dosage or refill reminders; telemedicine capability; certain incentives for scheduling, in extenuating circumstances[25]), and can be low risk under appropriate circumstances. Others promote access to healthy living (*e.g.,* vacuum cleaners, air conditioners, mattress covers, food vouchers), but not necessarily access to ''care.''[26] If an individual or entity is unsure whether a particular item or service would fit in the exception, or knows that the program does not fit in the exception but nevertheless believes it should be protected, the advisory opinion process is available. We reiterate, however, if the remuneration is not likely to induce a patient to select a particular provider, practitioner, or supplier, no exception is needed with respect to the beneficiary inducements CMP.

Comment: Some commenters recommended allowing in-kind, but not cash, incentives of nominal value, as described in the 2002 Special Advisory Bulletin. Others generally supported having some limits on the form or value of the incentive, but recommended considering what those limits would be in light of possible savings through the effective use of incentives. Other commenters recommended limiting the exception to providers who mainly serve low-income and rural patients so that other providers can't lure patients away without offering higher quality care.

Response: Consistent with our long-standing guidance, we agree with commenters who recommend that the remuneration cannot be cash or cash equivalents (such as checks or debit cards). We also explained above that the remuneration cannot take the form of copayment waivers (under this exception). We respectfully disagree that offerors should be limited to the monetary limits suggested in the 2002 Special Advisory Bulletin or the higher limits on nominal value we are announcing concurrently with this rule; we believe that higher-value remuneration can be warranted to promote access to care for some patients while remaining low risk. We also do not believe that the incentives protected

[23] For an example of an arrangement that included both lodging and transportation that we analyzed and found to be low risk, see OIG Advisory Opinion No. 11–01.

[24] In addition, to the extent the services qualify as preventive services, the preventive care exception could be available. That exception to the beneficiary inducements CMP specifically permits the provision of preventive care as a form of incentive, as long as it is not tied to the provision of other reimbursable services. *See* § 42 CFR 1003.110.

[25] An inducement to one patient to move an appointment in order to promote access by a different patient could be protected by the exception, in limited circumstances. Under the commenter's example, Patient A is retired, and Patient B works during business hours. Patient A receives the incentive to remove a barrier (an appointment that conflicts with Patient B's job) to Patient B's access to care. Thus the incentive promotes Patient B's ability to receive care. However, offering remuneration to all of a provider's patients who agreed to accept appointments at certain times would not necessarily promote access to care and could pose more than a low risk of harm to Federal health care programs.

[26] We note that these forms of remuneration might be protected by a different exception if provided to beneficiaries in financial need. *See* discussion of proposed regulation interpreting section 1128A(i)(6)(H), below.

by this exception should be limited to low-income and rural patients. While patients in those categories might be more likely to need remuneration to facilitate their access to care, many other patient populations also could have such a need. For example, regardless of income or geography, patients might need a device that reminds them to take medication. Thus, we do not believe these suggested limitations would be appropriate.

Comment: One commenter was concerned that use of the term ''patient'' might not allow the exception to cover plan sponsors or Medicaid MCOs (the plan-enrollee relationship). The commenter requested that the exception specifically recognize the role played by sponsors or MCOs and protect these efforts from the prohibition.

Response: The statutory exception uses the term ''patient,'' and the beneficiary inducements CMP prohibits influencing individuals to order or receive items or services payable by Medicare or a State health care program from a particular provider or supplier. At the time the individual would receive such item or service, the individual would be a ''patient.'' As we explained above, plan sponsors or other insurers may not raise the same concerns as providers and suppliers that bill Federal health care programs. If incentives given by these entities are not likely to induce the patient to use a particular provider, practitioner, or supplier, the beneficiary inducements CMP would not apply. (We note that differentials in coinsurance and deductible amounts as part of benefit plan designs that encourage patients to use in-network providers are protected by section 1128A(i)(6)(C) of the Act.)

Comment: Commenters expressed differing views on whether incentives offered in connection with CMS programs or models to which a waiver of the CMP does not apply should be separately protected. One commenter suggested a specific exception for participants in payment and delivery models, including medical homes, bundled payments, or other care coordination models. Another suggested an exception for all risk-bearing entities (such as MCOs) because they are already accountable for cost. One commenter generally supported extending this exception to CMS demonstration programs. Another commenter disagreed, stating that separately protecting ACOs would cause an uneven playing field with large ACOs compared to smaller provider groups. Another commenter suggested a middle ground, noting that new payment models do not always meet the terms of the exception (promoting access and being low risk). Therefore, the commenter recommended, if the exception were to generally extend to these models, that the models must incorporate key principles to qualify as low risk, including quality metrics, transparency requirements, and mechanisms to support patient access to a full range of treatment options.

Response: We recognize that the Department is testing different models and methods for improving quality while reducing cost. We acknowledge that CMS's new models and demonstration programs have additional or different oversight and accountability than some other programs, such as traditional fee-for-service Medicare. Participants in some of these programs, such as the MSSP or the Bundled Payment for Care Improvement initiative have access to waivers of certain fraud and abuse laws, including the beneficiary inducements CMP, for certain arrangements. If a program does not have an applicable waiver, we believe that all entities seeking to rely on the exception must meet its terms. Parties with access to waivers may still elect to avail themselves of this exception if they meet all conditions.

Comment: A number of commenters noted that CMP exceptions are not incorporated into the anti-kickback safe harbors and requested a parallel safe harbor for this exception. One commenter specifically requested that adherence support incentives be included in a safe harbor, with suitable safeguards. Another commenter requested that a safe harbor be developed for certain MCOs that would be similar to the patient incentive waiver in MSSP. Another commenter requested that the exception be expanded to allow remuneration to providers (*e.g.,* for remote patient monitoring). Another requested that the exception allow hospitals to help skilled nursing facilities or other long-term–care-facilities with portions of the cost of dispensing expensive medication.

Response: Commenters are correct that beneficiary inducements CMP exceptions do not provide protection under the anti-kickback statute. For a number of reasons, however, we decline to create a parallel safe harbor in this final rule. First, we did not propose such a safe harbor during this rulemaking and decline to adopt such a safe harbor without additional public comment. Further, this exception applies only to remuneration offered to beneficiaries, and we believe that the risk of fraud and abuse would be too high to generally protect remuneration offered to providers or suppliers under these standards. However, some such arrangements could be protected under existing safe harbors. For example, we proposed and are finalizing in this rule a safe harbor for local transportation. Commenters frequently mentioned transportation as needed for access to care. We will continue to monitor the changing health care delivery landscape and will consider appropriate safe harbors in the future. Any future proposals regarding additional safe harbors to protect specific types of remuneration that promote access to care and pose a low risk of harm to Federal health care programs and beneficiaries would be made through notice and comment rulemaking. In the meantime, individuals or entities are able to request protection from sanctions under the anti-kickback statute for specific arrangements through our advisory opinion process.

3. Retailer Rewards

In the Proposed Rule, we proposed to incorporate into our regulations the statutory exception added by section 6402(d)(2)(B) of the ACA, which creates an exception to the beneficiary inducements CMP for retailer rewards programs that meet certain criteria. We proposed to use the statutory language as the text for our regulation, and we proposed interpretations of the terms ''retailer'' and ''coupons, rebates, or other rewards;'' what it means to transfer items or services on equal terms to the general public; and what it means for items or services to not be ''tied to the provision of other items or services'' reimbursed in whole or in part by the Medicare or Medicaid programs. We are finalizing the language, as proposed, and we set forth responses to comments received below.

General Comments

Comment: One commenter referred to OIG's existing guidance permitting gifts of nominal value, which permits items worth $10 or less, or items valued at $50 in the aggregate for a beneficiary on an annual basis. The commenter believes that, for a retailer rewards program that meets the three criteria for this exception set forth in section 6402(d)(2)(B) of the ACA, OIG could adopt a higher and more flexible standard than the existing nominal value standard. This comment appears to imply that the retail reward exception would be subject to some monetary value limit.

Response: As we have explained in previous rulemakings and guidance, and as we discuss in greater detail above, if remuneration (other than cash or cash equivalents) is ''nominal in value,'' then

it is not prohibited by the statute, and therefore no exception is necessary.[27] Thus, remuneration that meets the criteria set forth in the retailer rewards exception need not be nominal in value, and remuneration that is nominal in value need not meet the criteria of an exception.

Comment: A commenter wanted OIG to clarify that this provision of law preempts any analogous state restrictions on retailer rewards.

Response: The retailer rewards exception creates a pathway for retailers to include Medicare and Medicaid beneficiaries in their rewards programs without violating a specific Federal law: the beneficiary inducements CMP. It does not create an exception to or preempt any other Federal law or any State law (unless such State law incorporates the Federal law by reference).

Comment: One commenter argued that OIG should eliminate all penalties for the use of retailer rewards because the benefit to the beneficiary outweighs any benefit to the retailer. Another commenter suggested that OIG should clearly permit and protect incentives that combine components of different exceptions within the Proposed Rule. As an example, the commenter suggested that a patient adherence tool could be linked with a retailer reward program.

Response: The beneficiary inducements CMP prohibits certain inducements to Medicare and Medicaid beneficiaries and includes certain exceptions to that prohibition. The statute and its exceptions are designed to protect beneficiaries and Federal health care programs. The retailer rewards exception eliminates penalties under this law for reward programs that meet each of the exception's criteria; we decline to eliminate penalties for rewards programs that do not meet all of the criteria of the exception. The same is true for other exceptions: remuneration that meets each of the criteria of any other exception are also protected. However, remuneration that implicates the statute and does not meet all criteria set forth in an exception may be subject to penalties. Further, remuneration will not be protected if it meets some criteria of one exception, and some criteria of a different exception. The remuneration needs to qualify for protection under only one exception, but it must meet all of that exception's criteria. It is possible that a patient adherence tool (depending on the type of ''tool'') could be a reward permitted under a retailer rewards program. However, it would have to meet all of the criteria, including not being tied to the provision of other items or services reimbursable by Medicare or State health care programs. Certain common items could be useful in patient adherence (*e.g.,* scales, pill dispensers, books) and could be protected under the exception. A more detailed discussion of what might constitute ''other rewards'' appears below.

Coupons, Rebates, or Other Rewards From a Retailer

The first criterion of the statutory exception provides that the free or less-than-fair-market-value items or services must ''consist of coupons, rebates, or other rewards from a retailer.'' We proposed to interpret these terms as follows: We proposed to interpret ''retailer'' as an entity that sells items directly to consumers. We also proposed that individuals or entities that primarily provide services (*e.g.,* hospitals or physicians) would not be considered ''retailers,'' and we solicited comments on whether entities that primarily sell items that require a prescription (*e.g.,* medical equipment stores) should be considered ''retailers.'' We proposed to interpret a ''coupon'' as something authorizing a discount on merchandise or services, such as a percentage discount on an item or a ''buy one, get one free'' offer. We proposed to interpret ''rebate'' as a return on part of a payment, with the caveat that a retailer could not ''rebate'' an amount that exceeds what the customer spent at the store. We proposed to interpret ''other rewards'' primarily as describing free items or services, such as store merchandise, gasoline, frequent flyer miles, etc.

''Retailer''

Comment: Many commenters raised concerns or sought clarification about the proposed interpretation of ''retailer.'' Commenters suggested that ''retail community pharmacies'' (as defined at section 1927(k)(10) of the Act[28]) and entities that interact with or serve beneficiaries (including independent or small pharmacies and other suppliers) be included in the interpretation of ''retailer'' because excluding these entities would place them at a disadvantage compared to big box pharmacies. Others wanted clarification as to whether online retailers qualify as ''retailers.'' Further, a commenter recommended that the term ''retailer'' not exclude any entity that sells a single category of products directly to individuals. Commenters asserted that the definition of ''retailer'' should not exclude entities that primarily sell items that require a prescription. Commenters were concerned that entities that sold a mix of items and services, including retail pharmacies, would have difficulty in determining whether they are retailers.

Response: We intend to finalize our proposal to interpret ''retailer'' in accordance with its commonly understood meaning: an entity that sells items directly to consumers. We continue to believe that a ''retailer'' does not include individuals or entities that primarily provide services. We believe that this interpretation can include independent or small pharmacies (and that pharmacies do not ''primarily'' provide services) and online retailers, and that it can include entities that sell a single category of items. However, we reiterate that the retailer rewards program must meet all of the exception's criteria to be protected. We believe that it may be difficult for an entity that primarily sells a single category of products to meet the criterion that the offer of items or services not be tied to other reimbursable services if, for example, the entity sells only (or mostly) items that are reimbursable by Federal health care programs.

Comment: One commenter sought clarification as to whether retailers are the only entities that can provider retailer rewards. Specifically, the commenter asked whether manufacturers could offer or transfer to patients any retailer rewards acquired or paid for by the manufacturer.

Response: As set out by Congress, the exception protects items or services ''from a retailer.'' Thus, nonretailers, including manufacturers, may not provide retailer rewards under this exception.

Comment: Another commenter understood that physicians were not retailers but encourages efforts that allow physicians to understand when rewards would be available to their patients.

Response: Unlike some exceptions to the beneficiary inducements CMP, the

[27] *See, e.g.,* the explanation of ''nominal in value'' concept in connection with the preventive care exception. 65 FR 24400, 24410–11 (Apr. 26, 2000).

[28] The Medicaid statute states that the term ''retail community pharmacy'' means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term- care-facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

retailer rewards exception does not prohibit advertising or marketing. Retailers are free to inform physicians directly or through media outlets about the availability of their rewards programs.

Comment: Some commenters disagreed with interpreting retailer to exclude entities that primarily provide services. Specifically, some commenters stated that there is no statutory justification to differentiate retailers that primarily provide services and those that do not. These commenters believe that the distinction between the two groups is therefore unjustified and puts big box retailers at a competitive advantage over pharmacies that also provide services. In addition, a commenter stated that it is unclear whether the retail components of hospital systems (*e.g.,* retail pharmacies) would be retailers. Another commenter had concerns about beneficiaries being excluded from rewards programs based strictly on their choice of pharmacy.

Response: As we explain above, we consider pharmacies to be retailers, whether the pharmacy is part of a ''big box'' retailer or is a stand-alone pharmacy. Most common definitions of ''retailer'' refer to selling ''goods'' to the public, not services. We did not propose to exclude entities that provide both items and services; we proposed to exclude individuals and entities that primarily provide services and thus typically would not be considered to be retailers, such as physicians or hospitals. If a hospital system has a separate retail component, whether it is a convenience store or a pharmacy, then that component could have its own rewards program if it met the exception's remaining criteria.

''Reward''

Comment: Commenters supported a broad and flexible definition of ''other rewards.'' One commenter believes that the proposed interpretation of ''other rewards'' as ''primarily . . . describing *free* items or services'' is too limited and should also include reduced-price items and services. Another commenter recommended that ''other rewards'' include in-kind benefits, including gift cards, educational information or programs, preventive care services, and retail-based initiatives to increase access to care (*e.g.,* providing diabetes educational events to customers).

Response: Our Proposed Rule stated our belief that ''other rewards'' would ''primarily'' be in the form of free items or services; this was not a strict limitation. We believe the majority of reduced-price items or services would fall under the proposed interpretation of coupon or rebate. The concept of ''other reward'' is broad: if the item or service meets the three criteria listed in the regulation, it can be protected. As we stated in the Proposed Rule, ''other rewards'' can include rewards such as gasoline discounts, frequent flyer miles, and items purchased in the retailer's store. To address specific examples provided by commenters, there is no reason why educational information or programs could not be ''other rewards'' (if they would be remuneration at all). Health care items or services can be ''other rewards,'' but the reward cannot be in the form of a copayment waiver; copayment waivers would not meet the third criterion of the exception, as explained below.

Offered or Transferred on Equal Terms

The second criterion requires that the items or services be offered or transferred on equal terms to the public, regardless of health insurance status. We proposed that this criterion would exclude programs that are targeted to patients on the basis of insurance status (*e.g.,* if a reward could be obtained only by Medicare beneficiaries).

Comment: Generally, commenters sought clarification as to the extent of the availability of the retailer reward to the general public that the OIG would require. Specifically, a commenter wanted clarification that it is appropriate for retailers to require consumers to complete an enrollment process as long as the related retailer rewards are offered on equal terms to the general public. One commenter recommended that this criterion be interpreted in a manner that prohibits targeting individuals of a particular health plan. Similarly, another commenter stated that retailers should be allowed to mail or email retailer rewards to existing customers as long as the communication is not specifically targeting government beneficiaries (*e.g.,* the commenter suggested that retailers should be able to offer a promotion targeted to patients with a particular disease state). Other commenters stated that the program should be broadly available to patients to discourage cherry picking and offered equally to the public regardless of health insurance status.

Response: The retailer reward must be offered to everyone regardless of health insurance status. The general public must have the same access to, and use of, the retailer reward as the retailer's insured customer base. This criterion does not, however, prohibit a retailer from having an enrollment process —as long as the terms of enrollment, and the terms of earning and redeeming rewards, do not vary based on insurance status or plan. A rewards program targeted to patients with a particular disease state would need to meet the requirement that the reward not be tied to other reimbursable items or services, as described below.

Not Tied to Other Reimbursable Items or Services

The third statutory criterion, which we are finalizing here, requires that the offer or transfer of the items or services not be tied to the provision of other items or services reimbursed in whole or in part by Medicare or an applicable State health care program. We proposed that this criterion require the rewards program to attenuate any connection between federally reimbursable items or services both in the manner in which a reward is earned and in the manner in which the reward is redeemed. Thus, we proposed that the reward could not be conditioned on the purchase of goods or services reimbursed in whole or in part by a Federal health care program and should not treat federally reimbursable items and services in a manner that is different from that in which nonreimbursable items and services are treated. On the ''redeeming'' end of the transaction, we proposed that rewards programs in which the rewards themselves are items or services reimbursed in whole or in part by a Federal health care program would not be protected.

Comment: Some commenters believed that OIG's interpretation of the third criterion is overly restrictive. One commenter stated that this criterion should be interpreted to prohibit a retailer reward that focuses on health care items and services only when a discount on one covered health care item or service is tied to the purchase of a second ''other'' covered health care item or service. Specifically, the commenter asserts that the statute does not require the reward to be equally applicable to health care and non-health care items or services. The commenter also does not believe that nonreimbursable items or services must be treated the same as reimbursable items or services when earning rewards. Therefore, the commenter disagreed with the statement in the preamble to the Proposed Rule that the reward (how it is earned or redeemed) should not treat federally reimbursable items and services in a manner that is different from that in which nonreimbursable items and services are treated. One commenter recommended that we not interpret the criterion to prohibit the reward from being tied to the provision of the same service. Another commenter

asserted that the proposed interpretation would prohibit entities from offering rewards for adhering to therapy or drug regimens. With respect to prescriptions, another commenter believed that having the criterion apply to both the earning and redeeming side of the transaction to be unnecessary and counterproductive because patients should be encouraged and incentivized to obtain prescribed medicines and other medical products.

Response: We respectfully disagree with several of the commenters' interpretations of, and recommendations with respect to, this criterion. The statutory criterion, which we adopt here, limits the exception as follows: ''the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under title XVIII or a State health care program (as defined in section 1128(h)).'' The ''reward'' cannot be tied to the provision of other reimbursable items. If a customer accumulates rewards (or preferentially accumulates rewards) based only on purchases of federally reimbursable items, the reward is tied to the provision of other reimbursable items because without purchasing those reimbursable items the customer would not earn a reward. Thus, for example, this criterion would not be met if a pharmacy had a rewards program that offered two points for every dollar spent on prescription copayments, but one point for every dollar spent elsewhere in the store. Likewise, if the reward were to take the form of a copayment waiver (or a $20 coupon off of a copayment), the reward would be tied to the purchase of a reimbursable item (the item for which the copayment is waived or discounted). In contrast, if the reward were a $20 coupon to be used on anything in the store, the coupon could, without violating the criterion, be redeemable a copayment. The coupon cannot, however, be limited to a reduction in price on a reimbursable item or service.

Comment: One commenter stated that the statute permits retailer rewards in the form of free or discounted health care items and services, not just non-health care items and services. A commenter asserted that the statute provides that retailer rewards may be offered as long as they are not tied to other covered items or services. The commenter sought confirmation that retailer rewards may take the form of discounts on covered health care services.

Response: As discussed above, the reward may not take the form of discounts specific to health care items or services that are reimbursed in whole or in part by Medicare or a State health care program. The reward can be a discount that could be used on anything in the store (including covered items or services), or can be specific to nonreimbursable items. If the retailer offered or gave a reward that was a free or discounted item or service covered by Medicare or a State health care program, but did not seek reimbursement for the item or service, the reward could be protected (as long as it was not tied to another reimbursed item). For example, a retailer could not have as a ''reward'' a free box of test strips that a patient could obtain only when filling an insulin prescription. However, if a retailer offered a rewards program such that if a patient spent a certain amount of money in the store over the course of the year, the patient could obtain a blood pressure monitor for free, that blood pressure monitor could be a protected reward as long as the retailer did not bill Medicare or a State health care program for it.

Comment: One commenter supported OIG's proposal that offering a $20 coupon to transfer prescriptions would not meet this criterion because such a reward influences beneficiaries who may accept less effective medication, substandard service, or be unduly overcharged by the retailer.

Response: We agree with the commenter that coupons to transfer prescriptions would not be protected under this exception. However, we do not agree with the commenter's analysis. The commenter asserts that the remuneration should not be protected because it might influence the beneficiary to choose a particular provider. However, all rewards programs might influence a beneficiary to choose a particular provider or supplier; if the remuneration wouldn't be likely to influence a beneficiary to choose a particular provider or supplier, no exception would be necessary because the remuneration would not implicate the beneficiary inducements CMP. Thus, the exception, which mirrors the statutory language, protects rewards programs that meet specific criteria, even though they might influence a beneficiary to choose a particular provider or supplier, because the criteria set forth in the exception provide sufficient safeguards to make the remuneration low risk. The remuneration used as an example by the commenter could not be protected by the exception because it fails to meet the criteria that prohibits tying the remuneration to purchasing a reimbursable item or service.

Comment: One commenter believed that OIG was inconsistent in its interpretation of similar criteria between the retailer rewards exception and the financial-need exception. According to the commenter, the financial-need exception requires the remuneration to have a connection to the patient's medical care and focus on health care items and services. With retailer rewards, the commenter stated that OIG did not focus on health care items and services. Instead, it applies the criterion to all items and services, including non-health care items and services.

Response: The financial-need-based exception has different criteria than the retailer rewards exception; both exceptions are statutory, and the statutory criteria are being finalized here. Both have a requirement that prohibits tying the offer or transfer of an item or service to the purchase of another reimbursable item or service. But in the financial-need-based exception, the item or service given must be reasonably related to the patient's medical care. The statute does not include such a requirement in the retailer rewards exception. In the retailer rewards exception, a program could involve a rebate, a coupon for health and beauty items, or a free toy. As long as the customer is not required to purchase a federally payable item or service to earn or redeem the reward, the type of item or service is not limited. The section below on the financial-need-based exception explains the different requirements that apply to the remuneration protected under that exception.

4. Financial-Need-Based Exception

We proposed to incorporate a third new statutory provision, added at 1128A(i)(6)(H) of the Act, which excepts from the definition of ''remuneration'' the offer or transfer of items or services for free or less than fair market value if the items and services are not advertised or tied to the provision of other items or services reimbursed by the Medicare or State health care programs (including Medicaid); there is a reasonable connection between the items or services and the medical care of the individual; and the recipient has been determined to be in financial need. We proposed, and are finalizing, regulatory text that mirrors the statutory language. We will continue to assess the need for additional flexibility in the future.

Several commenters generally supported the proposed exception and the approach OIG took when interpreting the statutory terms in the Proposed Rule. Others, while generally supporting the exception, urged OIG to interpret it more expansively, allow additional flexibility, and not include

certain restrictive criteria. We discuss these comments further below.

General

Comment: Some commenters noted that there could be overlap between this exception and the exception for remuneration that promotes access to care and poses low risk.

Response: We agree that there can be some overlap among exceptions. In addition to the exception cited by the commenter, the preventive care exception defined at 42 CFR 1003.110 shares some similarities with the financial-need-based exception. However, there are also distinctions among these exceptions. For example, the financial-need-based exception does not require that the remuneration ''promote access to care,'' or ''promote the delivery of preventive care,'' and those two other exceptions do not require that the recipient of the remuneration have a financial need. Remuneration might meet some criteria of multiple exceptions, but it is protected only if it meets all criteria of any one exception.

Comment: One commenter requested that the exception be carefully tailored to make clear that providers and suppliers are not *required* to provide free items or services to patients.

Response: The financial-need-based exception, like all other exceptions to the beneficiary inducements CMP, carves out certain things that otherwise would be prohibited remuneration from the definition of ''remuneration,'' when certain conditions are met. The exceptions do not impose any affirmative obligations on providers or suppliers to provide free items or services, waive copayments, or implement any program that involves giving anything of value to beneficiaries; rather, the exceptions describe the circumstances under which such gifts or benefits are not prohibited by the beneficiary inducements CMP.

''Items or Services''

We proposed to interpret the term ''items or services'' to exclude cash or instruments convertible to cash.

Comment: One commenter expressly supported precluding providers from paying cash to patients.

Response: We agree with the commenter and intend to interpret ''items or services'' as excluding cash, or cash equivalents (instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards).

Prohibition on Advertising

We proposed to include the statutory requirement that the items or services offered or transferred under the exception may not be offered as part of any advertisement or solicitation. We received some comments and questions about this requirement.

Comment: One commenter, though recognizing that the prohibition on advertising is statutory, recommended that OIG not include it in the regulation, claiming that it violates the First Amendment to the Constitution. The commenter suggested that there is no legitimate reason to prohibit informing the public about programs that could reduce costs for financially needy patients. The commenter stated that if OIG keeps the prohibition, it should impose the least restrictive means necessary (*e.g.,* allowing an entity to announce the availability and nature of the assistance, and directing the patient to other resources (such as a Web site or phone number) for more information.

Response: The prohibition on advertising of the incentive, copayment waiver, or other item or service has been in the statute for other exceptions since section 1128A(a)(5) was enacted in 1996. For the same reasons set forth above in connection with the safe harbor for Part D cost-sharing waivers, we respectfully disagree with the commenter's view that the advertising prohibition violates the First Amendment. As we explain below, we believe this exception is intended to protect remuneration given on a case-by-case basis, when a need is identified. It is not intended to encourage patients to seek care (in contrast to the exception for remuneration that incentivizes preventive care). In the section above regarding the local transportation safe harbor, we explain that the prohibition on advertising does not prohibit a provider or supplier from informing patients that an item or service is available, when done in a targeted manner. For example, if a physician learns that a financially needy patient lives alone and has trouble remembering which medication to take at what time, the physician can offer the patient a tool or service to help. However, providers and suppliers wishing to avail themselves of the protection offered by this exception cannot advertise in the media, or post information for public display or on Web sites about the availability of free items or services that the provider or supplier would seek to have this exception protect.

Comment: Some commenters requested that OIG clarify that the sliding fee discount programs that FQHCs are required to communicate do not constitute marketing.

Response: As we acknowledge elsewhere in this final rule, we understand that health centers that have a FQHC designation are required to make patients aware of the sliding fee discount program. Such required communications would not constitute marketing (for purposes of this exception), nor would the required discount program be prohibited remuneration under the CMP.

Not Tied to the Provision of Other Reimbursed Services

The statutory exception provides that the item or service being offered or transferred must not be tied to the provision of other reimbursed services. We proposed interpreting this limitation as not protecting offers or transfers of items or services that a provider or supplier conditions on the patient's use of other services that would be reimbursed by Medicare or a State health care program. We received comments and questions about this criterion.

Comment: Commenters requested clarification about how this condition applies to FQHCs and asked that we clarify that it does not extend to service discounts required from health centers designated as FQHCs. Another commenter noted that health centers designated as FQHCs are required to provide discounts on the basis of a patient's ability to pay, and asked that OIG clarify that FQHCs can continue to provide reimbursable services after providing such discounts.

Response: As we explain elsewhere in this final rule, we understand that health centers designated as FQHCs are required by law to establish sliding fee discounts for patients below certain income levels. Such billing policies were not prohibited before, and this exception would not change that. This exception only expands upon what providers and suppliers can do to help their patients in financial need.

Comment: Commenters asked about remuneration, such as lodging or transportation, that is expressly tied to receiving a service from a particular provider.

Response: Programs that offer lodging or transportation that is conditioned on receiving a particular service are ''tied'' to the particular service and would not be protected under this exception. However, other exceptions, such as the exception that allows remuneration that promotes access to care and poses a low risk of harm could apply, as could the anti-kickback safe harbor related to local transportation.

Comment: Some commenters requested clarification of ''other'' reimbursed services. One suggested that the remuneration can be connected to a reimbursable item or service, but can't be conditioned on the purchase of a second covered service. Another commenter asked us to clarify that the provider could continue to provide treatment in the future, even after giving remuneration in the past.

Response: The statute, and the regulation text, as it is being finalized, does not protect offering or giving items or services that are tied to the provision of other reimbursable services. As discussed in greater detail below, the item or service must be reasonably connected to the patient's medical care. Thus, at a high level, we agree with the comment that the remuneration can be connected to a reimbursable service as long as it is not conditioned on the purchase of a reimbursable service. With the exception of items or services provided by FQHCs or certain other entities that are required by law to be discounted, it seems unlikely that the remuneration offered under this section would be discounted reimbursable items or services themselves. Other than waiving the copayment amount (which would not be protected by this exception but could be protected by the exception at section 1128A(i)(6)(A) of the Act), there is no easy way to discount a reimbursable item or service. It is possible that the provider or supplier could give the item or service for free, and not bill Medicare, a State health care program, or the beneficiary for it. For example, if a financially needy diabetic patient were to run out of test strips and needed an immediate supply before a refill could be authorized, the pharmacist could give the patient an extra package of test strips and not bill the patient or payor for them. This free supply is not tied to another item or service, because, in the example, the patient could not get a refill at that time. The free supply does not require the patient to purchase a prescription or anything else from the pharmacy at that time or in the future. In other words, we recognize that providers or suppliers may have ongoing relationships with the patients to whom they may give free or discounted items or services under this exception. What this limitation prohibits is tying the purchase of a reimbursable item or service to the offer of the free item or service. Thus, using a different version of the example above, if the pharmacy had a practice of offering financially needy patients a free package of test strips (or any other item, whether or not it is reimbursable) each time the patient filled a prescription there, the remuneration would not be protected under this exception because it would be tied to filling the prescription.

Reasonable Connection to Medical Care

We explained in the Proposed Rule that the requirement that remuneration offered have a ''reasonable connection to the medical care of the individual'' must be interpreted in the context of this particular exception. This exception is not designed to induce the patient to seek additional care, but rather to help financially needy individuals access items or services connected to their medical care. We proposed interpreting ''medical care'' as the treatment and management of illness or injury and the preservation of health through services offered by the medical, dental, pharmacy, nursing, and allied health professions. We also proposed that for remuneration to be ''reasonably connected'' to medical care, it must be reasonable from a medical perspective and reasonable from a financial perspective. We received comments on each of these concepts.

Reasonable From a Medical Perspective

Comment: Some commenters argued that OIG should broadly interpret the idea of reasonable connection to medical care for FQHCs, in particular, since they provide their patients a wide variety of items (*e.g.,* diapers, car seats, strollers, baby formula, school supplies, toys, food, clothing, books, weight monitors, gas cards, and glucose monitors).

Response: In the context of this particular condition, we decline to treat FQHCs any differently than other providers or suppliers. We recognize both that FQHCs treat a particularly vulnerable population and that the distribution of items mentioned by commenters very likely benefits that population. However, this exception serves a particular purpose, the advancement of medical care for the financially needy individual, and therefore protects only remuneration related to a particular patient's medical care. Some of the examples above would not qualify (strollers, school supplies, and usually toys or clothing). Others possibly could qualify, depending on individual circumstances. It is possible, for example, that car seats, diapers, specialized clothing, baby formula or particular food items, books, weight monitors, gas cards, and glucose monitors could be reasonably connected to a particular patient's medical care (as explained in more detail in response to a later comment below). However, we note that other exceptions and published guidance could be applicable to items that do not qualify for this exception. For example, non-monetary remuneration of nominal value (as announced herein, $15 per item or $75 in the aggregate per year) is not prohibited. Likewise, under section 1128A(i)(6)(D), a health center (or other provider or supplier) can offer items or services to incentivize preventive care. Thus, a stroller or school supplies, among other items, can be offered to patients who attend necessary preventive care appointments.

Comment: Commenters urged us to deem remuneration to be reasonably connected to medical care when a medical professional (*e.g.,* a pharmacist, physician, care management team, or a generally accepted professional practice) determines it is connected to medical care, is important to patient success, or would benefit treatment or adherence to treatment.

Response: We agree that a medical professional is generally in the best position to determine that an item or service is reasonably connected to the care that professional is providing, including achieving a favorable treatment outcome. However, we emphasize that the medical professional must keep in mind the purpose of this exception when judging whether a reasonable connection to the patient's treatment exists. For example, the medical professional cannot give patients sporting equipment (such as a bicycle or basketball hoop) on the basis that the patient needs more exercise. Likewise, it would not be reasonable for a provider to give tickets to an entertainment event or a gift card for a spa on the basis that the patient is suffering from anxiety or depression.

Comment: Commenters made specific requests for a determination that certain items and services are reasonably connected to medical care, including transportation and lodging for a transplant patient and companion, bicycle helmets and other safety devices for children treated for injuries, and provision of most items connected to the wellness and health needs of patients, such as blood pressure cuffs, patient engagement apps, biomonitoring devices, and mobile devices as necessary to meet patients' various health needs.

Response: All of the listed items or services could be reasonably connected to a particular patient's medical care. However, they might not meet other prongs of the exception. For example, providing lodging to a transplant patient might be reasonably connected to his or

her medical care, but it also makes the offer of the free item or service (the lodging) contingent on receiving another service (the transplant) from the provider. This exception is designed to be patient-specific, so whether something is reasonably connected to a patient's medical care must be determined on a case-by-case basis. Further, the offer or transfer of the item or service must meet all criteria of the exception to be protected. We again note, however, that if the remuneration is nominal in value (as, for example, a patient engagement app might be), then it would not implicate the statute and would not need an exception to protect it.

Comment: Commenters made suggestions about general circumstances that would indicate remuneration is reasonably connected to medical care. One commenter agreed with circumstances we proposed (treatment benefit, lack of access to treatment absent payment resources, and others). The commenter also recommended permitting remuneration that is likely to enhance treatment outcomes. Others recommended remuneration that could lead to preservation of health and avoidance of injury, or improvement of nutritional status. Similarly, some commenters recommended preventive measures and items that support the structure and function of the body. Others recommended interpreting the medical connection requirement broadly, to encompass anything that could advance or improve care. Some commenters supported our suggestion in the Proposed Rule that we develop criteria that take into account a patient's unique physical, behavioral, and financial circumstances. Another commenter noted that imposing specific standards to define ''reasonably connected'' would be detrimental to the goal of the exception, because ''reasonable'' is a subjective standard and should involve patient-specific determinations.

Response: We believe that the phrase ''reasonable connection to medical care of the individual'' can be interpreted broadly. It can include items related to prevention of illness or injury, if specifically pertinent to a particular patient's medical care, as well as items related to medical treatment (*e.g.,* extra bandages for wound care). Items crucial to a patient's safety (such as car seats for infants) are reasonably connected to medical care. However, not everything beneficial to a patient is connected to medical care. For example, school backpacks, while beneficial to the children, are not connected to medical care. Those types of items might be permissible under a different exception (*e.g.,* the preventive care exception, if a practice offered backpacks to children who come in for required vaccines), but not under this one. Sometimes it is clear that an item is not connected to medical care, while in other circumstances that same item might be covered. For example, giving toys to children typically will not be reasonably connected to medical care. However, for certain children (*e.g.,* children experiencing developmental delays or recovering from certain illnesses or injuries that require therapy for fine motor skills), ''toys'' that reinforce treatment or aid in improving a health condition could be reasonably related to that individual patient's medical care. As we explain above, we believe that the medical professional working with the patient is in the best position to determine what is reasonably connected to his or her patient's medical care, but we emphasize that this exception does not protect items and services that are essentially for entertainment or other nonmedical purposes.

Reasonable Connection From a Financial Perspective

Comment: Some commenters recommended that we abandon the concept of remuneration having a reasonable connection to medical care from a financial perspective. One commenter suggested that this criteria does not appear in the statute, and financial criteria should affect only eligibility. Another commenter thought that the limit on ''disproportionately large'' remuneration would stifle the provision of assistance, and that we should rely on the medical aspect of reasonably connected to care.

Response: We decline to adopt the commenters' suggestion to abandon the condition of financial reasonableness. If a provider or supplier gives remuneration that has a high financial value, it is less likely to be ''reasonably'' connected to the medical care (and also unlikely to be given in the absence of a tie to additional services). For example, if a practitioner is treating an obese patient, the patient might benefit from an item or service connected to weight loss. An item such as an expensive electronic tablet with a weight loss program app (along with all of the other functionality available on such a tablet) would not be reasonable financially, but a less expensive item (electronic or paper-based), with similar information for the patient related to his or her medical care, might be. Moreover, the concept of excluding remuneration of disproportionately high value is not new; our regulatory exception to allow incentives for preventive care excludes ''[a]n incentive the value of which is disproportionally large in relationship to the value of the preventive care service (*i.e.,* either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).'' 42 CFR 1003.110.

Comment: Some commenters requested clarification of what it means to be disproportionately large. One asked that we provide detailed retail value limits, compared to the medical benefit to a beneficiary. Another commenter suggested that the term is ambiguous and asked about specific examples, such as providing disease management services or having a nurse follow up with a patient by telephone. Another commenter agreed that disproportionately large items and services could lead to inappropriate inducements but questioned where to draw lines. If the lines are too specific, they might disrupt the incentive to innovate (new technology might be developed that would meet congressional intent but would be precluded by use of certain language/restrictions).

Response: We decline to provide specific retail value for something that is disproportionately large. We also agree that we do not want to draw specific lines because needs vary among patients, and technology changes over time. Something that is very expensive today might be inexpensive (but still useful) in 10 years. Moreover, certain items or services could prevent much larger medical costs in the long (or short) run. For example, following a hospital discharge, particularly in a post-surgical context, a hospital might provide a financially needy beneficiary with items or services to ensure his home is safe for his recovery. It is important to consider whether the cost of the item or service is proportional to the possible harm it is designed to prevent. For example, offering a diabetic patient compression stockings could be reasonable from a financial perspective, but paying for a subscription to a long-term meal preparation and delivery service for such a patient would not be. On the other hand, providing meal deliveries for a limited period of time after a patient is discharged after a debilitating procedure might be reasonable from both a medical and financial perspective. Disease management programs could fit in the exception. For example, if a physician practice or clinic had a disease management program for asthma, and gave asthma patients free items to monitor or manage their breathing or

oxygen levels, or provided other services, and the free items or services met the other criteria of the exception, they would be protected.

Individualized Determination of Financial Need

We proposed to incorporate the statutory requirement that the items or services may be provided only ''after determining in good faith that the individual is in financial need.'' We proposed to interpret this provision as requiring an individualized assessment of the patient's financial need, in good faith, on a case-by-case basis. We proposed that such an assessment would require the use of a reasonable set of income guidelines, based on objective criteria that would be uniformly applied. We further proposed that the individual or entity offering the items or services should have flexibility to consider relevant variables in setting standards. We noted that we were considering whether to require documentation of the financial need assessment as a condition of the exception.

Comment: Commenters who addressed the issue generally objected to the potential requirement that patient need be documented. Commenters suggested that detailed documentation is burdensome, may require extensive time and effort, and might deter providers from offering assistance.

Response: While we are not requiring any specific documentation of financial need, we do expect that entities offering these items would do so in accordance with a set policy that is uniformly applied. Moreover, if an entity were under investigation and asserted this exception as a defense, it would have to be able to demonstrate compliance with the requirement to make a good faith determination of financial need. A written policy describing the standards and procedures used for establishing financial need, together with evidence that this written policy was followed, would be useful in making such a demonstration.

Comment: Several commenters suggested that entities be permitted to continue using their current processes for determining need. One commenter stated that some Medicaid programs require pharmacies to accept as true patient statements of inability to pay coinsurance amounts. Another recommended that FQHCs' assessments based on the sliding fee discount schedule should suffice. Some commenters suggested that hospitals have longstanding policies for determining need, and they should not be required to use a different process. One commenter supported an individualized determination, on a case-by-case basis, but recommended that the providers have flexibility to consider relevant variables.

Response: We agree with most of these comments. While the financial need determinations must be done on an individual basis, we are not mandating any particular basis for determining need. We do expect entities to have a set policy, based on income or other factors, and to uniformly apply that policy. However, providers and suppliers have the flexibility to determine the appropriate policy for their own patient populations. We do not agree that a patient statement of financial need should suffice in every instance. A statement of inability to pay coinsurance may suffice for a Medicaid patient, because Medicaid patients have been screened for financial eligibility by the state. A provider may have other reasons to be comfortable in accepting a patient's own statement of financial need, such as being located in a low-income area and generally serving a financially needy patient population, or knowing that a particular family has very high medical expenses. However, a provider or supplier should not rely solely on a representation by the patient that he or she is in financial need, unless the provider or supplier has some independent basis for belief that such a representation is reliable.

Comment: One commenter recommended that OIG determine a uniform measure of need (*e.g.,* a specific percentage of the Federal Poverty Level, as proven by individual tax forms or wage statements). Another recommended not requiring any documentation of need, unless a patient would receive over $500 in assistance annually.

Response: We decline to adopt a uniform measure of need, and we also decline to adopt a minimum threshold of assistance before a determination of need is required. This exception is intended to protect items and services that, under certain conditions, are given to financially needy patients. Thus, providers and suppliers must adopt a standard that can be reasonably considered to reflect financial need and cannot simply ignore the last condition of the exception. We also explained above that we do not intend to require specific documentation of the actual determination of need for each patient, but that providers or suppliers using this exception as a defense would need to be able to prove they complied with their own standards. For example, if a physician's policy was that any patient on Medicaid is qualified for assistance, the simple fact that the patient's file shows Medicaid as the payor is sufficient documentation. However, the income or wealth of patients with Medicare as a payor varies greatly. Thus, a provider or supplier offering items or services to a Medicare patient would need some method to determine whether the patient qualifies as financially needy under the standards set by the provider or supplier.

5. First Fill of a Generic

We proposed to incorporate into our regulations the fourth new provision added at section 1128A(i)(6)(I) of the Act, which excepts from the definition of ''remuneration'' the waiver by a PDP sponsor of a Part D plan or MA organization offering MA–PD plans of any copayment that would be otherwise owed by their enrollees for the first fill of a covered Part D drug that is a generic drug. We proposed to rely on the definition of ''generic drug'' in the Part D regulations at 42 CFR 423.4. Further, because CMS already permits these waivers as part of Part D and MA plan benefit designs, we proposed that sponsors desiring to offer these waivers to their enrollees would be required to disclose this incentive program in their benefit plan package submissions to CMS. We proposed that this exception would be effective for coverage years beginning after publication of the final rule. However, because this final rule is being published after the deadline for submission to CMS of benefit plan packages for coverage year 2017), this exception is applicable to coverage years beginning on or after January 1, 2018. We have revised the regulation text accordingly.

Those who commented on this proposal generally supported it. We address some specific comments and recommendations below.

Comment: One commenter asked that we revise the text of the regulation to ensure that it applies to all sponsors of Part D coverage.

Response: We did not intend to exclude any sponsors of Part D coverage from this exception. To ensure that the exception applies to all Part D sponsors, we have replaced the reference to ''a sponsor of a Prescription Drug Plan under part D of Title XVIII or a MA organization offering a MA–PD Plan under part C of such title'' with ''a Part D Plan sponsor,'' as that term is defined in 42 CFR 423.4.'' For consistency with this change, we also replaced the reference to ''Prescription Drug Plan or MA–PD Plan, repectively'' with ''Part D plan (as that term is defined in 42 CFR 423.4).''

Comment: One commenter asserted that the definition we proposed for ''generic drug'' (at 42 CFR 423.4) would not include ''authorized generics,'' which are defined at 21 CFR 314.3. The commenter recommended we expand the definition to include authorized generics.

Response: As we explained in the preamble of the Proposed Rule, the purpose of this exception is to minimize drug costs by encouraging the use of lower cost generic drugs. As a form of lower cost generic drug, use of authorized generics would further this goal. Therefore, as long as these waivers are included in the Part D Plan sponsor's benefit plan package submission to CMS, waivers of the first fill of authorized generics may be included in the exception as well. We have revised the language in the final rule to reflect this change.

Comment: One commenter asked OIG to remind PDP and MA–PD plans that pharmacy reimbursement must remain sufficient to provide Medicare beneficiaries adequate access to care. The commenter stated that plans should not simply waive copayment amounts, which the commenter asserts would be at no cost to the plan but great cumulative cost to the pharmacies. The commenter also suggests that these waivers could create a financial incentive for pharmacies not to dispense generic drugs.

Response: Part D Plan sponsors submit their plan designs to CMS and negotiate terms with their network providers. Pharmacies can choose whether to be in the network and accept those terms. OIG does not have a role in setting pharmacy reimbursement via the Part D Plan sponsors. This statutory exception, which we are incorporating into regulations, confirms only that Part D Plan sponsors offering such waivers would not violate the beneficiary inducements CMP.

Comment: One commenter supported our proposal to require advance disclosure of any copayment waivers in Medicare plan benefit packages, as well as transparency of such programs to pharmacies, in order to allow pharmacies notice to decide if and how the pharmacies may agree to participate in Part D Plan sponsor's provider network and waiver program.

Response: We agree with the commenter that disclosure and transparency are important. We are finalizing the requirement that the waivers be included in the benefit design package submitted to CMS in the regulation.

D. Comments Outside the Scope of Rulemaking

We received several comments that are outside the scope of this rulemaking. For example, some commenters requested that we initiate new safe harbors, provide guidance on issues outside of the proposed safe harbors, and protect specific programs or initiatives outside of the proposed safe harbors. While we may consider these requests in future rulemaking, we also remind stakeholders that the advisory opinion process remains available for determinations on individual arrangements.

III. Provisions of the Final Regulation

This final rule incorporates most of the regulations we proposed in the Proposed Rule, but with some changes to the regulatory text.

We are finalizing, with certain revisions, both new safe harbors that we proposed in 42 CFR 1001.952(k): one to protect waivers or reductions in cost-sharing by pharmacies for financially needy beneficiaries, and one to protect waivers in cost-sharing for State- or municipality-owned emergency ambulance services. We also made a change was to the introductory language of subparagraph (k), expanding this safe harbor to all Federal health care programs. To implement the change where applicable, we are republishing subparagraph (k) in its entirety. We are finalizing the safe harbor to protect free or discounted local transportation, with some changes from the Proposed Rule. Two of the most frequent topics of comment were our interpretation of ''established patient'' and the distance limitation. In response to comments, we broadened our interpretation of ''established patient'' to encompass any patient who has made an appointment with the provider or supplier. We also revised our interpretation of ''local'' to include different distances for rural and nonrural areas, and we added a section applicable to shuttle services. We are finalizing the other safe harbors ((1) a technical correction to the referral services safe harbor; (2) arrangements between federally qualified health centers and MA organizations; and (3) discounts under the Medicare Coverage Gap Discount Program) as we proposed them in the Proposed Rule with minor, if any, changes.

We are finalizing all of the beneficiary inducements CMP exceptions, with certain changes. In the Proposed Rule, we did not propose regulatory text for the exception for remuneration that promotes access to care but poses a low risk of harm to patients and Federal health care programs. However, we proposed to interpret ''promotes access to care'' to mean that the remuneration improves a particular beneficiary's ability to obtain medically necessary health care items and services. We proposed to interpret the requirement that remuneration pose a low risk of harm to Federal health care program beneficiaries and programs to mean that the remuneration must: (1) Be unlikely to interfere with, or skew, clinical decision making; (2) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient safety or quality-of-care concerns. We are finalizing regulatory text that mirrors these proposals. The only changes we are making to any of the other four exceptions proposed in the Proposed Rule are the following changes to the exception relating to waivers of the copayment for the first fill of a generic drug: to incorporate a definition recommended by commenters of ''Part D Plan sponsor;'' to include ''authorized generic drugs'' in the exception; and to specify when the exception becomes effective. Otherwise, the text of each exception in the final rule is the same that we proposed in the Proposed Rule.

We are not finalizing the gainsharing CMP regulation that we proposed. We had proposed to codify the gainsharing CMP set forth in section 1128A(b) of the Act, which, as of October 2014, provided penalties for hospital payments to physicians to ''reduce or limit services'' (not only medically necessary services) to Medicare or Medicaid beneficiaries. We solicited comments on a narrower interpretation of the term ''reduce or limit services'' than we have previously held. However, section 512(a) of MACRA amended the language in quotes to insert the words ''medically necessary'' before ''services.'' Because of the amendment to the statute, we are unable to finalize the rule, as proposed. However, this statutory provision is self-implementing, and no regulatory action is required to make the change enacted in MACRA effective.

IV. Regulatory Impact Statement

We have examined the impact of this proposed rule, as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, and Executive Order 13132.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and,

if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects, *i.e.,* $100 million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold.

This proposed rule would implement or codify new and existing CMP exceptions and implement new or revised anti-kickback statute safe harbors. The vast majority of providers and Federal health care programs would be minimally impacted from an economic perspective, if at all, by these proposed revisions.

The changes to the safe harbors and CMP exceptions would allow providers to enter into certain beneficial arrangements. In doing so, this regulation would impose no requirements on any party. Providers would be allowed to voluntarily seek to comply with these provisions so that they would have assurance that participating in certain arrangements would not subject them to liability under the anti-kickback statute and the beneficiary inducement CMP. These safe harbors and exceptions facilitate providers' ability to provide important health care and related services to communities in need. We believe that the aggregate economic impact of the changes to these regulations would be minimal and would have no effect on the economy or on Federal or State expenditures.

Accordingly, we believe that the likely aggregate economic effect of these regulations would be significantly less than $100 million.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered small entities by having revenues of $7 million to $35.5 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The changes to the CMP exceptions and the the anti-kickback statute safe harbors would not significantly affect small providers as these changes would not impose any requirement on any party.

In summary, we have concluded that this final rule should not have a significant impact on the operations of a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under Titles XVIII or XIX or section B of Title XI of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. For the reasons stated above, we do not believe that any provisions or changes finalized here would have a significant impact on the operations of rural hospitals. Thus, an analysis under section 1102(b) is not required for this rulemaking.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million, adjusted for inflation. We believe that no significant costs would be associated with these revisions that would impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of $141 million (after adjustment for inflation) in any given year.

Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this rule would not significantly affect the rights, roles, and responsibilities of State or local governments.

V. Paperwork Reduction Act

The provisions of this final rule will not impose any new information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

List of Subjects

42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

42 CFR Part 1003

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

Accordingly, 42 CFR parts 1001 and 1003 are amended as set forth below:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 2. Section 1001.952 is amended by revising paragraphs (f)(2) and (k), and adding paragraphs (z), (aa), and (bb) to read as follows:

§ 1001.952 Exceptions.

* * * * *

(f) * * *

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants and is based only on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

* * * * *

(k) *Waiver of beneficiary copayment, coinsurance and deductible amounts.* As used in section 1128B of the Act, ''remuneration'' does not include any reduction or waiver of a Federal health care program beneficiary's obligation to pay copayment, coinsurance or deductible (for purposes of this subparagraph (k) ''cost-sharing'') amounts as long as all the standards are met within one of the following categories of health care providers or suppliers.

(1) If the cost-sharing amounts are owed to a hospital for inpatient hospital services for which a Federal health care program pays under the prospective payment system, the hospital must comply with all of the following three standards:

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed.

(iii) The hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the cost-sharing amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under Titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under Title V of the Act, the health care center or facility may reduce or waive the cost-sharing amounts for items or services for which payment may be made in whole or in part by a Federal health care program.

(3) If the cost-sharing amounts are owed to a pharmacy (including, but not limited to, pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) for cost-sharing imposed under a Federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if:

(i) The waiver or reduction is not offered as part of an advertisement or solicitation; and

(ii) Except for waivers or reductions offered to subsidy-eligible individuals (as defined in section 1860D–14(a)(3)) to which only requirement in paragraph (k)(3)(i) of this section applies:

(A) The pharmacy does not routinely waive or reduce cost-sharing amounts; and

(B) The pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts.

(4) If the cost-sharing amounts are owed to an ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and all the following conditions are met:

(i) The ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act;

(ii) The ambulance provider or supplier engaged in an emergency response, as defined in 42 CFR 414.605;

(iii) The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and

(iv) The ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.

* * * * *

(z) *Federally Qualified Health Centers and Medicare Advantage Organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a Medicare Advantage organization pursuant to a written agreement described in section 1853(a)(4) of the Act.

(aa) *Medicare Coverage Gap Discount Program.* As used in section 1128B of the Act, ''remuneration'' does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount Program established in section 1860D–14A of the Act, as long as all the following requirements are met:

(1) The discounted drug meets the definition of ''applicable drug'' set forth in section 1860D–14A(g) of the Act;

(2) The beneficiary receiving the discount meets the definition of ''applicable beneficiary'' set forth in section 1860D–14A(g) of the Act; and

(3) The manufacturer of the drug participates in, and is in compliance with the requirements of, the Medicare Coverage Gap Discount Program.

(bb) *Local Transportation.* As used in section 1128B of the Act, ''remuneration'' does not include free or discounted local transportation made available by an eligible entity (as defined in this paragraph (bb)):

(1) To Federal health care program beneficiaries if all the following conditions are met:

(i) The availability of the free or discounted local transportation services—

(A) Is set forth in a policy, which the eligible entity applies uniformly and consistently; and

(B) Is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;

(ii) The free or discounted local transportation services are not air, luxury, or ambulance-level transportation;

(iii) The eligible entity does not publicly market or advertise the free or discounted local transportation services, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

(iv) The eligible entity makes the free or discounted transportation available only:

(A) To an individual who is:

(*1*) An established patient (as defined in this paragraph (bb)) of the eligible entity that is providing the free or discounted transportation, if the eligible entity is a provider or supplier of health care services; and

(*2*) An established patient of the provider or supplier to or from which the individual is being transported;

(B) Within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area, as defined in this paragraph (bb); and

(C) For the purpose of obtaining medically necessary items and services.

(v) The eligible entity that makes the transportation available bears the costs of the free or discounted local transportation services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals; and

(2) In the form of a ''shuttle service'' (as defined in this paragraph (bb)) if all of the following conditions are met:

(i) The shuttle service is not air, luxury, or ambulance-level transportation;

(ii) The shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

(iii) The eligible entity makes the shuttle service available only within the eligible entity's local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 50 miles between that that stop and all providers or suppliers on the route; and

(iv) The eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals.

Note to paragraph (bb): For purposes of this paragraph (bb), an ''eligible entity'' is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items; ''established patient'' is a person who has selected and initiated contact to schedule an appointment with a provider or supplier to schedule an appointment, or who previously has attended an appointment with the provider or supplier; ''shuttle service'' is a vehicle that runs on a set route, on a set schedule; ''rural area'' is an area that is not an urban area, as defined in this rule;and ''urban area'' as: (a) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or (b) the following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 3. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

■ 4. In § 1003.110, the definition of ''remuneration'' is amended by revising the introductory text and paragraph (3) and adding paragraphs (5) through (9) to read as follows:

§ 1003.110 Definitions.

* * * * *

Remuneration, for the purposes of § 1003.1000(a) of this part, is consistent with the definition in section 1128A(i)(6) of the Act and includes the waiver of copayment, coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term ''remuneration'' does not include:

* * * * *

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented;

* * * * *

(5) A reduction in the copayment amount for covered OPD services under section 1833(t)(8)(B) of the Act;

(6) Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—

(i) Being unlikely to interfere with, or skew, clinical decision making;

(ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and

(iii) Not raising patient safety or quality-of-care concerns;

(7) The offer or transfer of items or services for free or less than fair market value by a person if—

(i) The items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(8) The offer or transfer of items or services for free or less than fair market value by a person, if—

(i) The items or services are not offered as part of any advertisement or solicitation;

(ii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a State health care program (as defined in section 1128(h) of the Act);

(iii) There is a reasonable connection between the items or services and the medical care of the individual; and

(iv) The person provides the items or services after determining in good faith that the individual is in financial need;

(9) Waivers by a Part D Plan sponsor (as that term is defined in 42 CFR 423.4) of any copayment for the first fill of a covered Part D drug (as defined in section 1860D–2(e)) that is a generic drug (as defined in 42 CFR 423.4) or an authorized generic drug (as defined in 21 CFR 314.3) for individuals enrolled in the Part D plan (as that term is defined in 42 CFR 423.4), as long as such waivers are included in the benefit design package submitted to CMS. This exception is applicable to coverage years beginning on or after January 1, 2018.

* * * * *

Dated: August 3, 2016.

Daniel R. Levinson,

Inspector General.

Approved: August 4, 2016.

Sylvia M. Burwell,

Secretary.

Note: This document was received by the Office of the Federal Register on November 18, 2016.

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Part IV

National Credit Union Administration

12 CFR Part 701

Chartering and Field of Membership Manual; Final Rule

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

RIN 3133–AE31

Chartering and Field of Membership Manual

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board is comprehensively amending its chartering and field of membership rules to maximize access to federal credit union services to the extent permitted by law, and to organize the rules in a more efficient framework. The amendments will implement changes in policy affecting: The definition of a local community, a rural district, and an underserved area; the chartering and expansion of a multiple common bond credit union; the expansion of a single common bond credit union that serves a trade, industry or profession; and the process for applying to charter, or to expand, a federal credit union.

DATES: The effective date of this final rule is February 6, 2017.

FOR FURTHER INFORMATION CONTACT: Matthew Biliouris, Deputy Director, or Robert Leonard, Director, Division of Consumer Access, or Rita Woods, Director, Division of Consumer Access South, Office of Consumer Protection, at the above address or telephone (703) 518–1140; or Senior Staff Attorney Steven Widerman, or Staff Attorney Marvin Shaw, Office of General Counsel, at the above address or telephone (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background
II. Summary of Comments on Proposed Rule
III. Regulatory Procedures

I. Background

NCUA's Chartering and Field of Membership Manual, incorporated as Appendix B to part 701 of its regulations (''Chartering Manual''),[1] implements the field of membership (''FOM'') requirements and limitations established by the Federal Credit Union Act (''the Act'') for federal credit unions (each an ''FCU'').[2] As amended by the Credit Union Membership Access Act of 1998 (''CUMAA''), the Act provides a choice among three charter types: a single common bond consisting of a group whose members all share the same occupational or associational common bond;[3] a multiple common bond in which each group has a distinct occupational or associational common bond among its own members;[4] and a community common bond among persons or organizations within a well-defined local community, neighborhood, or a rural district.[5]

To facilitate consumer access to credit unions and to enhance their delivery of services as the Act contemplates, the Board periodically modifies and updates the Chartering Manual to advance certain objectives. Among these are relief from undue burdens and restrictions on an FCU's ability to provide services to consumers who are eligible for FCU membership, especially to benefit those of modest means; enhancement of the menu of strategic options for FOM expansions; and maximization of competitive parity between federal and state charters to the extent allowed by law, while respecting the national system of dual chartering. To serve those objectives, the Board published a proposed rule in December 2015 requesting public comment on fifteen substantive modifications to the rules affecting each of the three FOM types that the Act authorizes.[6]

As explained below, this final rule will implement proposed modifications to the rule affecting: The definition of a local community, a rural district, and an underserved area; the expansion of a multiple common bond credit union; the expansion of a single common bond credit union that serves a trade, industry or profession; and the type and extent of information that must be submitted to support an application to charter or expand an FCU's FOM.

II. Summary of Comments on Proposed Rule

NCUA received approximately 11,380 comments on the proposed rule: 31 from national and regional credit union trade associations and leagues; 99 from individual FCUs; 14 from federally-insured state-chartered credit unions; 8291 from individual credit union members; 14 from national and regional bank trade associations; 6 from individual banks; 2925 from individual bank customers; and 6 from other commenters.[7] The commenters generally supported the proposed rule by a ratio of approximately 3 to 1, mostly without reference to a specific proposal and without suggesting alternatives or modifications.

A. Community Common Bond

The Act limits membership in a community credit union to ''[p]ersons or organizations within a well-defined local community, neighborhood, or rural district,''[8] directing the Board to establish criteria defining those terms for purposes of ''making any determination'' regarding such a credit union,[9] and to establish applicable criteria for any such determination.[10] The Act does not impose for any of the three community categories a maximum limitation on population or geographic size, thus supporting the Board's observation that ''there is no statutory requirement or economic rationale that compels the Board to charter only the smallest [well-defined local community] in a particular area.''[11]

To qualify as a well-defined local community (''WDLC'') or as a rural district, the Board requires a proposed area to have ''specific geographic boundaries,''[12] and for residents within those boundaries to interact or share common interests that signify a cohesive community. Since 2010, the Board has offered two ''presumptive community'' options that by definition meet the statutory criteria of a WDLC. Each is based on uniform, objective geographic units. One is a ''Single Political Jurisdiction . . . or any individual portion thereof'' (each an ''SPJ''), regardless of population.[13] The other is a single Core Based Statistical Area (''CBSA'' or ''a statistical area,'' or a portion thereof) as designated by the U.S. Census Bureau (''Census''), or a Metropolitan Division within a CBSA, subject in either case to a 2.5 million population limit.[14]

1. ''*Core Based Statistical Area*'' *Population Limit.* The existing 2.5 million population limit that applies to a community consisting of a CBSA, or a Metropolitan Division or other portion within, conforms to the population threshold by which the Office of Management and Budget (''OMB'') designates Metropolitan Divisions

[1] Appendix B to 12 CFR part 701 (''Appendix B'').
[2] 12 U.S.C. 1759.
[3] *Id.* § 1759(b)(1).
[4] *Id.* § 1759(b)(2)(A).
[5] *Id.* § 1759(b)(3).
[6] 80 FR 76748 (December 10, 2015).
[7] Among credit union- and bank-affiliated commenters combined, 98 percent of the 11,380 comments consisted of form letters, with minimal original content and often submitted by a third party vendor on the commenter's behalf.
[8] 12 U.S.C. 1759(b).
[9] *Id.* § 1759(g)(1)(A).
[10] *Id.* § 1759(g)(1)(B).
[11] 74 FR 68722, 68725 (Dec. 29, 2009).
[12] Appendix B, Ch. 2, § V.A.2.
[13] Appendix B, Ch. 2, § V.A.2.
[14] Appendix B, Ch. 2, § V.A.2. According to the Census, ''the term 'core-based statistical area' became effective in 2003 and refers collectively to metropolitan statistical areas and micropolitan statistical areas.'' *https://www.census.gov/geo/reference/gtc/gtc_cbsa.html#md.*

within a CBSA.[15] The proposed rule retained the 2.5 million limit, but solicited public comment on whether to adjust it, to what amount, and for what specific reasons.

The vast majority of commenters urged the Board to eliminate the population cap on statistical areas altogether because the Act does not mandate it. They maintained that an area's population is unrelated to what should be the paramount considerations in identifying a local community, namely, interaction or common interests among residents, and the FCU's ability and commitment to serve the area. The commenters also contended that, by imposing a population limit, the Board is substituting its judgment for Census data, by which CBSAs are designated without regard to population, and that population alone is not a source of undue risk to an FCU or to the National Credit Union Share Insurance Fund (''the Insurance Fund''). Finally, some commenters protested that a population cap on statistical areas puts FCUs at a competitive disadvantage compared to communities consisting of an SPJ, which are not limited by population.

Some commenters advocated increasing the present cap from 2.5 million to between 3.5 million and as much as 5 million, respectively, to ensure the long-term growth and viability of FCUs in general. Others urged increasing the population limit to match that of the most populous SPJ the Board has approved (Los Angeles County, CA, at 10 million), or that of the nation's most populous Metropolitan Statistical Area (New York-Newark-Jersey City, NY-NJ-PA Metro Area at 20 million). One commenter recommended linking the population limit to an appropriate index that would trigger periodic reevaluation and possible adjustment of the existing limit.

In contrast, dozens of commenters criticized the existing 2.5 million cap as being too high, urging that it be reduced. One insisted that the 2.5 million cap is not a credible ''indicator of common, close-knit interaction.'' Another predicted that an area as populous as 10 million could qualify as a local community as long as its residents ''interact in some way . . . within lines drawn by NCUA.'' Yet another criticized the Board for implying that the existing 2.5 million cap is too low only by comparison to the most populous SPJs the Board has approved (*e.g.,* Los Angeles County, CA, and Harris County, TX).

The Board finds considerable merit in commenters' suggestions to eliminate the population cap, increase the present population cap to a given amount, tie the cap to the population of a certain geographic unit, or administer any cap according to a framework of oversight and internal controls. Out of concern that the public should have notice and an opportunity to address such recommendations, as the Administrative Procedure Act requires,[16] the Board has decided to make no change to the existing 2.5 million population cap at this time. Instead, the Board will issue a proposal soliciting public comment on alternatives to modify the cap, and an alternative to the ''presumptive community'' options to form a WDLC.

2. ''*Core Area*'' *Service Requirement.* Since 2010, the Board has required a community consisting of a portion of a CBSA to include the CBSA's ''core area,'' [17] defined in practice as the most populated county or named municipality in a CBSA's title. The Act itself does not mandate any such requirement for a community. The proposed rule repealed the ''core area'' service requirement in favor of relying on NCUA's practice of annually reviewing an FCU's business and marketing plans, for the first three years following approval of a community charter expansion or conversion, to assess whether the credit union is adequately serving the intended beneficiaries of the requirement—namely low-income and underserved populations within an original or an expanded community.[18]

The majority of commenters favored repeal of the ''core area'' service requirement, primarily because it is not mandated by the Act and thus unnecessarily imposes an additional constraint on who credit unions can serve. They further speculated that relief from an obligation to serve a ''core area'' will give FCUs the flexibility to adapt to the specific area each initially is able to reasonably and safely serve, allowing it to establish and maintain a ''marketplace footprint'' there. Other commenters criticized the ''core area'' service requirement for dividing an otherwise viable community or excluding portions that would enhance its viability; for causing an FCU to sacrifice service to other areas within the chosen portion of a CBSA; and as a disincentive to serve populated urban areas due to the additional cost and resources of serving a ''core area.''

A few commenters suggested alternatives in lieu of applying a ''core area'' service requirement to a portion of a CBSA. One is to permit an FCU to develop a presence, reputation and services to enable it to later expand into the ''core area'' of a CBSA. The other is to defer to the National Federation of Community Development Credit Unions and to the Community Development Financial Institutions Fund regarding how best to identify and to provide service to low-income and underserved populations.[19]

In contrast, bank-affiliated commenters generally favored retaining the ''core area'' service requirement. One predicted that its absence would effectively permit ''redlining'' through formation of a community primarily consisting of wealthier areas within a CBSA, while excluding areas where low-income and minority populations are concentrated. Another urged the Board to retain the ''core area'' service requirement given that, unless expressly required by state law, credit unions typically are not subject to the Community Reinvestment Act, which requires financial institutions *other than credit unions* to publicly document service to people of modest means.[20]

What critics of repealing the ''core area'' service requirement overlook is that NCUA has in place a supervisory process to assess management's efforts to offer service to the entire community an FCU seeks to serve. NCUA holds credit union management accountable for the results of an annual evaluation that encompasses a community FCU's implementation of its business and marketing plans,[21] extending for three years after the credit union either is chartered, converts or expands. Experience confirms that the agency's evaluations are a more effective means of ensuring that the low-income and underserved populations are fairly served compared to the rest of the community, in contrast to a requirement forcing a credit union to serve the ''core area'' of the portion of a CBSA that comprises its community. The Board considered extending this review period to five years, but has declined to do so,

[15] *https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf* (at page 62).

[16] 5 U.S.C. 553(c).

[17] 75 FR 36257, 36260 (June 25, 2010).

[18] 80 FR at 76749.

[19] For Underserved Area purposes, the Act, at 12 U.S.C. 1759(c)(2)(A)(i), relies on the Community Development Banking and Financial Institutions Act, *id.* § 4702(16)(A), to define an ''investment area,'' which, among other things, can consist of an ''empowerment zone'' or ''enterprise community'' as defined by 26 U.S.C. 1391.

[20] 12 U.S.C. 2902(2)

[21] The results of an annual evaluation of an FCU's implementation of its business and marketing plans typically would be reflected in the ''findings'' or ''overview'' sections of an examination report, or in a ''Document of Resolution'' issued following an examination.

believing that three years is sufficient time to gauge a credit union's commitment to serve an original or expanded area, and that the additional two years of projections would be too stale to be probative.

Another relevant part of the supervisory process is the agency's mandate to consider member complaints alleging discriminatory practices affecting low-income and underserved populations, such as redlining, and to respond as necessary when such practices are shown to exist.

Having considered the comments addressing repeal of the ''core area'' service requirement, and because it is not a requirement mandated by the Act, the Board has decided to repeal it in view of credit unions' success in providing financial services to low-income and underserved populations without regard to where they are located within a community, *i.e.,* beyond its ''core area.'' This assessment is based on the periodic evaluations, overseen or conducted by the Office of Consumer Protection since 2010, of FCUs' implementation of their business and marketing plans.[22] In place of the ''core area'' service requirement, the final rule requires NCUA to continue these evaluations to ensure fair and adequate service to the low-income and underserved populations within a community consisting of a portion of a CBSA.

3. *Population Limit as Applied to a Portion of a ''Core Based Statistical Area''.* The existing rule disqualifies a *portion* of a CBSA as a WDLC when the population of the CBSA *as a whole* exceeds the 2.5 million population cap, even when the population of the portion *by itself* does not exceed that limit—an unintended consequence.[23] To correct this oversight, the proposed rule modified the ''statistical area'' definition to specify that in the case of a community consisting of a portion of either a CBSA or a Metropolitan Division within, the portion *by itself* must have a population of 2.5 million or fewer, regardless whether the CBSA or Metropolitan Division *as a whole* exceeds the limit.

The majority of commenters supported this technical remedy in order to prevent the unintended disqualification of a portion of a CBSA that falls within the population cap solely because the CBSA as a whole exceeds it. In that event, an FCU would have no recourse but to serve an area smaller than the portion it seeks to serve (*e.g.,* an SPJ consisting of a city or town). Although many commenters opposed the existing 2.5 million population cap as excessive, none opposed this proposal to narrowly apply the cap exclusively to the portion of a CBSA that an FCU designates as its community.

Having considered the comments addressing this proposal, the Board considers it an appropriate remedial initiative to limit to the population cap adopted in the final rule the portion of a CBSA a credit union seeks to serve.

4. *''Combined Statistical Area'' as a Well-Defined Local Community.* The existing rule designates two ''presumptive communities'' that by definition qualify as a WDLC—an SPJ regardless of population, and a CBSA subject to a 2.5 million population limit.[24] The proposed rule added a third ''presumptive community'': A Combined Statistical Area as designated by OMB,[25] subject to the same population limit. The 174 Combined Statistical Areas that OMB has designated each combine ''two or more adjacent CBSAs that have substantial employment interchange.''[26] As with any community an FCU seeks to serve, a Combined Statistical Area would be subject to NCUA's practice of periodically reviewing the FCU's implementation of its business and marketing plans to assess its capability of, and success in, serving its original or previously expanded community.

Scores of commenters supported the proposal to recognize Combined Statistical Areas as ''presumptive communities,'' concurring that OMB's approach in designating Combined Statistical Areas is consistent with NCUA's long-standing consideration of factors such as employment, commuting patterns and economic interaction to identify a WDLC. These commenters further contended that Combined Statistical Areas are appropriate ''presumptive communities'' according to social and economic integration among residents within them, apart from strict population and density numbers, because Combined Statistical Areas represent the same ''commonality of substantial employment interchange'' that an individual CBSA's residents must have.

In addition, commenters cited certain benefits of recognizing Combined Statistical Areas as ''presumptive communities.'' One is the flexibility to serve multiple counties located within a single Combined Statistical Area, or to expand a community beyond an individual CBSA's boundaries. Another is the opportunity for an FCU serving a single CBSA with a population less than 2.5 million to further expand in scope up to that limit. Another benefit is the addition of Combined Statistical Areas to the menu of safe and sound strategic options for an FCU to grow and survive once it reaches a saturation level within its present FOM.

Finally, one commenter supported the recognition of Combined Statistical Areas as ''presumptive'' communities as a ''welcomed change that is obviously within the confines [of the Act].'' Another cited an OMB pronouncement in support of Government agency use of Metropolitan and Micropolitan Statistical Area or Combined Statistical Area delineations to develop a non-statistical program, as long as the agency seeks public comment on the proposed use[27]—as the Board did in this rulemaking through the proposed rule.

Bank trade associations opposed recognizing Combined Statistical Areas as ''presumptive communities.'' One criticized the proposal as exceeding the reasonable definition of ''local.'' Others contended that a Combined Statistical Area necessarily is too expansive to be ''local'' because it ''represents larger regions'' that can encompass thousands of square miles crossing county and state borders. One opponent predicted that Combined Statistical Areas would be used to create state-wide FOMs, believing that this was not what Congress intended. Another claimed that Congress sought to impose narrow limits on areas a community credit union serves.

These commenters overlook certain facts that contradict the notion that a Combined Statistical Area is too expansive to be ''local.'' First, of the 174 designated Combined Statistical Areas, the 22 largest would not qualify as a WDLC because each, as a whole, exceeds the 2.5 million population cap. Second, the average geographic size among the 152 Combined Statistical Areas that would each qualify as a WDLC, at 4553 square miles, is comparable to the average geographic

[22] For communities with a population of less than 1 million, NCUA regional offices conduct the review of business and marketing plans to assess an FCU's service to the community as a whole, including low-income and underserved populations within. They report the results to the Office of Consumer Protection semi-annually. For communities with a population of 1 million or greater, the Office of Consumer Protection itself conducts the review and assessment.

[23] Appendix B, Ch. 2, § V.A.2. (''statistical area'' definition).

[24] 75 FR 36257 (June 25, 2010).

[25] OMB Bulletin No. 15–01 to Heads of Executive Departments and Establishments (July 15, 2015) at: *https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/1-01.pdf.*

[26] U.S. Census Bureau, *Geographic Terms and Concepts,* at: *https://www.census.gov/geo/reference/gtc/gtc_cbsa.html#md.*

[27] OMB Bulletin No. 15–01 *supra* note 24.

size among the 243 individual CBSAs the Board has approved since 2010, at 4572 square miles.

Having considered the comments addressing the proposal to recognize a Combined Statistical Areas as a ''presumptive community,'' the Board adopts the proposal given that a Combined Statistical Area simply unifies, as a single community, two or more contiguous CBSAs that each independently meet the existing rule's definition of a ''statistical area'' that presumptively qualifies as a WDLC. Accordingly, subject to the existing 2.5 million population limit for a CBSA, the rule adds to the ''statistical area'' definition ''all or an individual portion of . . . a Combined Statistical Area designated by the U.S. Office of Management and Budget.'' [28]

5. *Addition of an Adjacent Area to a Well-Defined Local Community.* The existing rule does not, for general use, give credit unions the option to submit a narrative, supported by objective documentation, that an FCU contends will demonstrate common interests or interaction among residents of a proposed community (the ''narrative model'').[29] The proposed rule allows credit unions to once again use a narrative approach supported by objective documentation to demonstrate that an area adjacent to a community consisting of an SPJ, a CBSA or a Combined Statistical Area qualifies as part of that local community. The credit union, using objective documentation, must demonstrate that the adjacent area is logically part of a WDLC that includes an SPJ, CBSA, or Combined Statistical Area due to common interests or interaction among residents on both sides of the perimeter. The expanded community still is subject to the applicable population limit. Any FCU has the option of pursuing a community charter that combines an adjacent area with all or a portion of an SPJ, CBSA or Combined Statistical Area. To support such an expansion, an FCU with a proven track record in serving an existing FOM may be permitted to use an agency-prescribed set of relaxed business plan requirements, as set forth in the final rule.[30] However, a credit union without an established track record of serving a community, such as a credit union converting to a community charter, will need to provide a full business and marketing plan.

Most credit union-affiliated commenters supported the proposal to permit a community credit union to add an adjacent area upon narrative proof of common interests or interaction among residents of the expanded community. They recommended that option as a logical advance in business development because it would allow an FCU to add an adjacent area without requiring it to discontinue serving its existing community. However, several commenters opposed the requirement that an FCU must support its application to add an adjacent area with a business plan demonstrating its post-expansion commitment and ability to serve the entire community.

Bank trade associations opposed the concept of permitting adjacent area additions to a community, regardless how common interests or interaction among residents is demonstrated, and in a few cases opposed it conditionally. Without specifying a substantive or procedural objection, some commenters asserted that the Board lacks statutory authority to implement the proposal. Another contended that, due to the breadth and scope of the banking industry, the adjacent areas the proposal addresses do not lack sufficient access to financial services. Still another complained that approval of an adjacent area addition on the basis of NCUA's qualitative assessment of a narrative would render the process non-transparent.

Two critical commenters conditioned their opposition to the proposal to allow adjacent area additions on certain modifications. The first would be to require the Board develop a complete record confirming that the proposed adjacent area meets six interaction or common interest characteristics among its residents, rather than accepting on its face the supporting information the credit union provides. The second would be, in each case, to require the Board to then publish a notice in the **Federal Register** inviting public comment on whether the proposed adjacent area is a WDLC.

The Act gives the Board broad discretion to define a WDLC for purposes of ''making *any determination*'' regarding a community credit union,[31] and to establish criteria to apply to any such determination.[32] Under that authority, the Board proposed a set of criteria that a narrative should address, and which NCUA staff would consider in evaluating an application to add an adjacent area to an existing community.[33] In contrast, the Act did not require NCUA to effectively subject each such application to a referendum by means of notice and an opportunity for the public to comment. In that event, the volume of community charter, conversion and expansion applications the agency's staff receives each year (an annual average of eighty-seven since 2010) would make it impracticable to seek public comment on each proposed adjacent area addition, and would needlessly consume agency resources. Further, a notice and opportunity to comment on each application, followed by agency review of the comments, would delay credit union service to the residents of the adjacent area in each case.

Having considered the comments addressing the proposal to permit an adjacent area addition to a community and, for that limited purpose, to accept narrative proof of common interests and interaction among residents, the Board has decided to adopt the proposal in the final rule.[34] In addition, the Office of Consumer Protection, or its successor, will separately issue guidance on the criteria introduced in the proposed rule that a narrative should address to support the addition of an adjacent area, and which the Board will consider in deciding an FCU's application to do so. The guidance may specify a certain number of criteria that, if met, would presumptively qualify an adjacent area for approval.

6. *Individual Congressional District as a Well-Defined Local Community.* Although not prohibited by statute, since 1999 the Board has maintained that Congressional districts and whole states do not qualify as a WDLC, even though both are well-defined.[35] In the December 2015 proposed rule, the Board reconsidered its policy and, as a result, proposed to recognize an individual Congressional district as a SPJ, thus qualifying each as a ''presumptive community'' without regard to population.[36] As with any other community charter application, the proposal required an FCU to support its application to serve a Congressional district with a business and marketing plan demonstrating its ability and

[28] Appendix B, Ch. 2, § V.A.2.

[29] In 2010, the Board abandoned the narrative model in favor of giving credit unions an option among ''presumptive communities'' that each by definition qualifies as a WDLC. 75 FR 36257, 36260 (June 25, 2010).

[30] 80 FR at 76750; Appendix B, Ch. 2, § V.B.

[31] 12 U.S.C. 1759(g)(1)(A) (emphasis added).

[32] *Id.* § 1759(g)(1)(B).

[33] 80 FR at 76772 (referring to the presence of an economic hub, quasi-governmental agencies, Government designated programs, shared public services and facilities, and colleges and universities).

[34] Appendix B, Ch. 2, § V.A.2.

[35] 63 FR 72012, 72013, 72037 (Dec. 30, 1998); Appendix B, Ch. 2, § V.A.2. *See also* 75 FR at 36258 (affirming that entire state is not acceptable as WDLC).

[36] Appendix B, Ch. 2, § V.A.1.

commitment to serve the entire community.

At least a thousand credit union-affiliated commenters supported the proposal to recognize Congressional districts as SPJs; only one opposed it.[37] The supporters emphasized that the Act never restricted Congressional districts from qualifying as a WDLC, thus giving the Board latitude to reconsider its original policy disqualifying them. One commenter characterized Congressional districts as the ''ultimate political jurisdictions'' because their average population of about 710,000 is far less than that of many SPJs, and less than the population threshold by which OMB may divide a CBSA into Metropolitan Divisions (2.5 million). Another suggested that a community consisting of an individual Congressional district should be allowed to encompass a certain radius of miles beyond the district's boundaries. In contrast, hundreds of bank-affiliated commenters opposed recognition of individual Congressional districts as SPJs.

The Board has considered the comments addressing the proposal to recognize an individual Congressional district as a ''presumptive community.'' Notwithstanding certain merits of the proposal, the Board has decided to defer action on it at this time, consistent with an incremental approach to introducing, and permitting credit unions to acclimate to, other significant community common bond enhancements adopted in the final rule (*e.g.,* Combined Statistical Areas, adjacent area additions, and an increased population limit and a new multi-state expansion limit on Rural Districts). As a result, the final rule does not designate an individual Congressional district as a ''presumptive community.''

7. *Commenters' Recommendations in Response to the Proposed Rule.* Several commenters initiated community common bond recommendations that the Board did not propose. The first commenter-initiated recommendation was that the Board accept as a ''presumptive community'' (in addition to CBSA and SPJ that the existing rule permits) *any* ''Federal, state or other statistical model'' an FCU chooses to designate as its community. The second recommendation was that the Board extend membership eligibility to non-profit organizations that provide services to the community a credit union serves, regardless whether the organization is headquartered or located there (as the existing rule requires). The third recommendation was that the Board accept for general use a narrative to demonstrate interaction or common interests among residents to support *any* application to charter, expand or to convert to a community credit union (not just in support of an adjacent area addition, as the final rule provides). The fourth recommendation was that the Board, by regulation, permit a multiple common bond credit union that converts to a community charter to add and serve new members from its *pre-conversion* select employee groups (''SEGs'') now located *outside* its community boundaries. This proposal would interpret the Act's ''grandfathered members and groups'' exception [38] to permit what would effectively be a ''once a SEG, always a SEG *regardless of common bond*'' policy allowing a multiple common bond credit union to retain those outside SEGs after it converts to a community charter.

The Administrative Procedure Act (''APA'') prohibits the Board from adopting these four recommendations in the final rule because the proposed rule did not introduce them for public comment, thus not ''provid[ing] sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.'' [39] Nor is any of the four recommendations a logical outgrowth of a proposal that *was* introduced for public comment in the December 2015 proposed rule. As a result, the public was not given reasonable notice and an opportunity to address these commenters' recommendations.

B. Rural District Definition

The Act does not mandate a population limit for a Rural District. However, to qualify as a Rural District, the existing rule restricts the area's total population to the *greater* of either 250,000 people *or* 3 percent of the population of the state in which the majority of the proposed Rural District's residents would be located.[40] In addition, either at least 50 percent of the proposed Rural District's population must reside in geographic units the Census designates as ''rural,'' *or* the proposed Rural District's population density cannot exceed 100 persons per square mile.[41]

1. *Population Limit.* The proposed rule modified the present Rural District definition to increase the population limit from 250,000 to 1 million persons to ensure that the population of a Rural District is sufficient to provide a level of operating efficiencies and scale that would make the area attractive as a strategic option, and to facilitate credit unions' statutory responsibility to provide consumers, including persons of modest means who may reside in rural areas, with access to our national system of cooperative credit. The proposed rule also omitted as redundant the alternative population limitation of 3 percent of the population of the state in which the majority of the Rural District's residents would be located.

Nearly all of the credit union-affiliated commenters who addressed the proposed population increase to 1 million supported it, provided the Board does not eliminate the population cap on Rural Districts altogether. They dismissed the cap as superfluous in view of other qualifying criteria—the existing minimum population density and ''rural'' designation options and, if it were adopted, the multi-state expansion limit. They further contend that the characteristics of a Rural District do not change much as its population fluctuates. Conversely, one commenter conditioned its support for a 1 million population cap on elimination of the population density criterion, arguing that (at 100 persons per square mile) it is unduly low in any case.

Others believed that the sole criterion to qualify as a Rural District should be a credit union's ability to serve the area, as demonstrated by business and marketing plans, including via online services to members. To expand a Rural District, these commenters urged that the decisive factor should be evidence of the contiguous area's economic and social ties to the pre-expansion Rural District. One commenter suggested permitting an area to qualify as a Rural District so long as the Census does *not* classify it as either an ''urban area'' or

[37] The single credit union-affiliated opponent alleged a lack of ''commonality'' among residents of a Congressional district because it is ''skewed for political reasons to enable election of a certain party's candidates.''

[38] The ''grandfathered members and groups'' exception provides that ''Notwithstanding [section 1759(b)]—(i) any person or organization that is a member of any Federal credit union as of August 7, 1998, may remain a member of the credit union after August 7, 1998; and (ii) a member of any group whose members constituted a portion of the membership of any Federal credit union as of August 7, 1998, shall continue to be eligible to become a member of that credit union, by virtue of membership in that group, after August 7, 1998.'' 12 U.S.C. 1759(c)(1)(A).

[39] 5 U.S.C. 553(b)(3), 706(2)(A); *United States Telecom Ass'n* v. *Federal Communications Commission,* 2016 WL 3251234 (slip op. page 10); *CSX Transp., Inc.* v. *Surface Transp. Bd.,* 584 F.3d 1076 (D.C. Cir. 2009); *Ass'n of Private Sector Colleges and Univ.* v. *Duncan,* 681 F.3d 427 (D.C. Cir. 2012).

[40] Appendix B, Ch. 2, § V.A.2.

[41] *Id.*

an ''urban cluster.''[42] Instead of relying on ''rural'' versus ''urban'' distinctions, another commenter urged the Board to treat a Rural District the same as the final rule treats an adjacent area addition to a community, *i.e.,* allow the use of a narrative to demonstrate interaction and common interests among proposed Rural District residents.

Apart from the preference to eliminate the Rural District population cap, several commenters predicted that a 1 million population cap would open up consumer choice for a cooperative form of financial institution, helping credit unions to serve the low wage workers who dominate certain rural markets. Others emphasized the difficulty of delineating the borders of a Rural District versus an urban community, due to scattered population hubs and widely dispersed individuals and businesses, and urged the Board to modify its rules to facilitate credit union service to those areas.

Six bank-affiliated trade associations objected to the proposal because it quadrupled the Rural District population cap. These commenters stated that the proposal was an unreasonable interpretation of the statutory terms ''rural'' and ''local.'' They expressed concern that credit unions will exploit the increased population cap to combine densely populated and thinly populated areas into a single area to meet the population density limit, and to create state-wide fields of membership.

To limit Rural District expansions, one commenter urged NCUA to require the *majority* of persons within a proposed Rural District to reside in geographic units the Census designates as ''rural.'' Another commenter opposed the use of similar Consumer Financial Protection Bureau (''CFPB'') designations of ''rural'' counties, which would qualify approximately 3 out of 4 counties in the commenter's state for a Rural District expansion, believing that such a result would exceed a reasonable interpretation of ''local'' and ''rural.'' On the assumption that the Act requires a Rural District to be ''local,'' a commenter maintained that ''a Rural District encompassing a large region inherently would lack interaction or common interests among residents and thus inconsistent with the Act.''

These views rely on a pair of misconceptions: That ''local'' as used in section 1759(b) and (g) modifies ''rural district,'' when in fact it does not; and that a ''local'' area and a ''rural'' area necessarily share similar characteristics, which they inherently do not. In any case, a Rural District by its very nature typically covers an area that is too large to be considered ''local.''

As the proposed rule explained, a Rural District must have a population sufficient to enable it to provide a level of operating efficiencies and scale that will make it attractive to credit unions as a strategic option. In that regard, a commenter questioned why a population of 1 million is needed to achieve that objective when, according to the commenter, community banks manage to serve far fewer than 1 million people located in rural areas. Another commenter expressed concern that NCUA will exploit the need for ''operating efficiencies'' to raise the Rural District population cap beyond 1 million.

Having considered the comments addressing the Rural District population cap, the Board has decided to set the rural district population cap at 1 million, as proposed. The Board believes this higher limit will achieve a ''balance . . . between permitting rural districts to be large enough to be economically viable but not unreasonably large taking into account the purpose of the rural district,''[43] and will bring affordable financial services to portions of the country that would not otherwise meet the requirements of a WDLC.

A higher population cap is supported by the Board's experience since 2013 with eight credit unions, in four different states, serving Rural Districts with an average population of 536,646.[44] The ability of these credit unions to bring affordable financial services to more populated areas has convinced the Board that a population cap should permit additional growth opportunities in rural areas. These opportunities would assist credit unions located in areas where residents are unable to readily interact or share common interests to support a WDLC—which is subject to a much higher population cap—even though these residents need access to affordable financial services.

The existing rule provides an alternative population limit of 3 percent of the population of the state in which a majority of a rural districts residents are located. Under that alternative, the Board has approved 8 rural districts above the general population limit of 250,000. Moreover, that alternative already allows a rural district with a population of at least 1 million in one state, and of at least 800,000 in another. Having set a 1 million precedent in one state, the purpose of the alternative limit also justifies a *fixed* 1 million population cap for the other 49 states—a high enough cap to accommodate not only the hub area within a rural district, but also the surrounding population of potential members, to support the rural district's economic viability.

In view of this objective, a 1 million cap is appropriate because it strikes an appropriate balance between economic viability and an excessive population. It also leaves credit unions that already serve a Rural District, as well as those that would consider doing so, sufficient flexibility going forward to maintain economic viability and to maximize penetration of the potential membership base.

Most importantly, an increased cap will enhance consumer access to our national system of cooperative credit, particularly those of modest means in rural areas, who may otherwise lack access to a not-for-profit cooperative credit union. In this regard, the Board finds it compelling that in 97 percent of non-metropolitan counties, more than 50 percent of the population is either low, moderate, or middle income.[45] Accordingly, the final rule increases the Rural District population cap to 1 million, while still requiring credit unions to demonstrate an intent and ability to serve the entire area.

Bank-associated commenters speculated that larger regions would lack interaction or common interests among their residents. What these commenters overlook is that these defining characteristics of a WDLC do not apply to a Rural District. Rather, primarily due to the sparsely distributed population in rural areas,[46] the defining characteristic of a Rural District necessarily is population density.

The Board believes that increasing the population limit on rural districts is warranted by the contemporary economic realities of serving sparsely populated areas. The penetration rate among community charters typically is five percent. As a result, for a credit union serving a rural district to thrive, a sufficiently large population base is essential to enable it to offer financial services economically. Although some commenters believe that the higher limit would give credit unions an unfair

[42] For Census identification of ''urban areas'' and ''urban clusters,'' see *https://www.census.gov/geo/reference/ua/urban-rural-2010.html.*

[43] 78 FR 13460, 13462 (Feb. 28, 2013).

[44] Each of these eight Rural Districts was approved under the existing rule despite a population in excess of 250,000 because, in each case, its population was less than 3 percent of the population of the state in which the majority of the Rural District's residents were located.

[45] *https://www.ffiec.gov/geocode/help3.aspx*

[46] 74 FR 68722, 68723 (December 29, 2009).

competitive advantage, the reality is that credit unions in rural districts are subject to restrictions on who they may serve, unlike other types of financial institutions. The Board believes that the objective of expanding opportunities for credit unions to serve more consumers in rural areas outweighs any perceived impact on competition. The Board's concern about excessive expansion of rural districts is addressed below.

2. *Multi-State Expansion Limit.* The existing rule permits the expansion of a Rural District beyond the boundaries of the state in which the FCU maintains its headquarters. To achieve consistency with Census recognition of expansive rural areas while appropriately limiting multi- state expansion, the proposed rule revised the present Rural District definition (population limit plus either sparse population density or a ''rural'' designation) to confine a Rural District's expansion to the boundaries of the states that are *immediately contiguous* to the state in which the FCU approved to serve the Rural District is headquartered (*i.e.,* not to exceed the outer perimeter of the layer of states immediately bordering the headquarters state).

Relatively few commenters addressed the proposed multi-state expansion limit. Some of the credit union-affiliated commenters opposed the multi-state expansion limit as redundant, suggesting that it should be eliminated in view of the population cap, which would function as an appropriate check on overexpansion. Conversely, others advocated retaining the multi-state expansion limit, provided the population cap on Rural Districts is eliminated. One commenter urged that the sole criterion for approving a Rural District should be the credit union's ability to serve an area lacking in access to credit union service, including by technological means. The few bank commenters who addressed the proposed multi-state expansion limit opposed the concept of multi-state Rural Districts altogether, dismissing it as a means to effectively allow state-wide and multi-state FOMs.

In contrast to these comments, the Board's purpose is to have dual limitations that each serve a unique purpose—one on population, the other on geographic area size. Therefore, having considered the comments addressing the proposed multi-state limit on Rural District expansions, the Board has decided to adopt it without alteration in the final rule. Accordingly, the final rule provides that, to qualify as a Rural District, an area's boundaries must ''not exceed the outer boundaries of the states that are *immediately contiguous* to the state in which the credit union maintains its headquarters (*i.e.,* not to exceed the outer perimeter of the layer of states immediately surrounding the headquarters state).'' [47]

C. Underserved Areas

The Act authorizes the Board to allow multiple common bond credit unions to serve members residing in an ''underserved area,'' provided the FCU establishes and maintains a facility ''in'' the area.[48] To qualify as ''underserved,'' an area must, among other criteria, be ''underserved . . . by other depository institutions . . ., based on data of the Board and the Federal banking agencies.'' [49] In the absence of a specific test or criteria to assess such ''underservice,'' the Board developed a ''concentration of facilities ratio'' (''COF ratio'') [50] that it has relied upon to determine whether a proposed area is underserved by other depository institutions.

1. *Exclusion of Non-Depository Institutions and Non-Community Credit Unions from Concentration of Facilities Ratio.* To prevent dilution and distortion of the COF ratio, as well as to strictly adhere to the letter and the spirit of the ''depository institutions'' definition,[51] the proposed rule excluded non-depository banks (*e.g.,* trust companies, which do not accept deposits from the general public) [52] and non-community credit unions (*e.g.,* multiple common bond credit unions other than those already serving an Underserved Area) from the COF ratio. By definition or in practice, neither is capable of serving the general public of a proposed Underserved Area.

Of the commenters who specifically addressed the proposed non-depository bank and non-community credit union exclusions from the COF ratio, most opposed the COF concept altogether, denouncing it as: Flawed, unduly cumbersome and incapable of producing a meaningful analysis; the cause of unnecessary disapprovals; and a disincentive to serve an Underserved Area.[53] However, assuming the Board would retain the COF ratio, 41 credit union-affiliated commenters supported both exclusions.

Other commenters urge that once a Government agency designates an area as ''underserved,'' the Board should not require the FCU to also demonstrate that the area is ''underserved by other depository institutions'' (even though the Act mandates exactly that); should disregard the number of depository institutions already serving the area (even though the Act mandates the opposite); and should exempt underserved areas from the population cap that applies to a CBSA. These commenters maintained that greater flexibility concerning Underserved Area criteria would reduce burden—presently a disincentive for credit unions to expand service to an Underserved Area. However, these commenters overlooked the Act's explicit requirement that an area be ''underserved by other depository institutions'' [54] regardless of the other statutory criteria, in order to qualify as an Underserved Area.

One commenter asked the Board to clarify how shared branches would count to determine whether an area is ''underserved by other depository institutions'' (*i.e.,* whether each shared branch *participant* counts as an individual depository institution, or the shared branch as a whole counts as a single depository institution regardless of the number of participating institutions). As an incentive to serve Underserved Areas, another commenter asked the Board to develop and make public a list of Underserved Areas that qualify under the applicable criteria (effectively pre-approving them) in

[47] Appendix B, Ch. 2, § V.A.2.

[48] 12 U.S.C. 1759(c)(2).

[49] *Id.* § 1759(c)(2)(A) citing *id.* § 461(b)(1)(A). The Act relies on the Community Development Banking and Financial Institutions Act to define ''depository institution.'' *Id.* § 4702(16). By definition, a ''depository institution'' is insured and includes credit unions. *Id.* § 461(b)(1)(A)(iv).

[50] 73 FR 73392 (Dec. 2, 2008). Using census tracts as the unit of measure, the concentration of facilities ratio compares the concentration of depository institution facilities among the population within the non-''distressed'' portions of the proposed area against the concentration of such facilities among the population of the area as a whole. 73 FR at 73396. Appendix B, Ch.3, § III.B.3. An area qualifies as underserved by other depository institutions when the concentration of facilities ratio within its non-''distressed'' census tracts exceeds the concentration of facilities ratio within the census tracts of the area as a whole.

[51] 12 U.S.C. 461(b)(1)(A).

[52] As identified in FDIC's ''Summary of Deposits Survey,'' *e.g., https://www.fdic.gov/news/news/financial/2015/fil15024.pdf.*

[53] As the Board explained when it proposed the COF ratio: ''CUMAA did not specify a methodology for determining whether a proposed area meets the 'underserved . . . by other depository institutions' test; instead, it broadly refers to unspecified 'data of the [NCUA] Board and the Federal banking agencies.' 12 U.S.C. 1759(c)(2)(A)(ii). In the decade since CUMAA, raw data has accumulated within government on branch locations and the volume of business in certain products and services, but meaningful and reliable data on these points has only recently become readily accessible. This data makes it possible to quantify and compare the presence of financial institution facilities in a given area. The proposed rule suggests [the COF ratio as] a flexible methodology that relies on publicly available population data and data on the location of financial institution branches.'' 73 FR 34366, 34369 (June 17, 2008). *See also* 73 FR 73392, 73396 (Dec. 2, 2008).

[54] 12 U.S.C. 1759(c)(2)(A)(ii).

order to conserve the resources credit unions otherwise must devote to identifying Underserved Areas.

Although many bank-affiliated commenters opposed the concept of the COF ratio altogether, one supported the proposed exclusions. Having considered the comments addressing the proposed exclusions from the COF ratio, the Board considers the proposal an appropriate improvement and, therefore, implements both exclusions in the final rule.

2. *Alternatives to Identify Areas ''Underserved by Other Depository Institutions.''* As alternatives to using the COF ratio to assess whether a proposed area is underserved by other depository institutions, the proposed rule permitted use of ''underserved county'' designations by the CFPB,[55] as well as a metric of a credit union's own choosing provided it is based on NCUA or other Federal banking agency data.[56] In addition, the proposed rule invited commenters to identify other methodologies and Federal banking agency data that would be useful to objectively determine whether an area is ''underserved by other depository institutions.''

Credit union-affiliated commenters suggested various metrics to use in addition to, or instead of, the COF ratio to assess the existing level of service by depository institutions already present in a proposed Underserved Area. These included the CFPB's ''underserved'' county designations, and Home Mortgage Disclosure Act (''HMDA'') data indicating the number of depository institutions that meet a minimum ratio of mortgage loans extended to residents within an area versus borrowers from outside, and to persons below a certain credit score limit. In many cases, the suggested metric is generic because the commenter did not specify the data the metric would rely on and/or the source of the data.[57] A single bank commenter opposed the use of alternative metrics altogether, finding it inappropriate to allow credit unions to rely on a metric of their own choosing.

Having considered the comments suggesting alternative metrics to determine whether a proposed area is underserved by other depository institutions, the Board has decided to accept the CFPB's ''underserved county'' designations as a proxy for a determination of ''underservice.'' The Board also will consider an FCU-chosen metric, provided it is based on NCUA or Federal banking agency data. An example of such a metric would be relevant data from the publicly available reports of Community Reinvestment Act examinations conducted by the Federal Deposit Insurance Corporation (''FDIC''), the Office of the Comptroller of the Currency or the Board of Governors of the Federal Reserve System, or from HMDA data collected by these agencies.[58]

Accordingly, the final rule provides that ''a proposed area will qualify as 'underserved by other depository institutions' if it is designated as, or is within, an 'underserved county' according to data produced by the CFPB. . . . NCUA will make a list of 'underserved counties' available on its Web site.''[59] Alternatively, the final rule permits a credit union to submit for approval ''a metric of its own choosing that is based on NCUA or other Federal banking agency data, [that] establishes to NCUA that the proposed area is 'underserved by other depository institutions.'[60]

3. *Commenters' Recommendations in Response to the Proposed Rule.* In response to the proposed rule, a few commenters initiated Underserved Area recommendations of their own. The Board can adopt a regulatory proposal only when, and to the extent, it is authorized by law, and then only if it is supported by rational and reasonable policy conclusions as reflected in the rulemaking record.[61]

The first commenter recommendation was that the Board, by regulation, permit any charter type to add an Underserved Area, whereas the existing rule permits only a multiple common bond credit union to do so. To allow any charter type to serve an Underserved Area would require Congress to amend the Act, which presently limits Underserved Area additions to FCUs in the ''the field of membership category of which is described in [section 1759(b)(2)],'' *i.e.,* exclusively a ''multiple common-bond credit union.''[62] Pending such an amendment to the Act, the Board lacks the authority to adopt the recommendation to allow *any* charter type to add an Underserved Area.

The second commenter recommendation was that the Board permit ''other technical means,'' beyond what the existing ''service facility'' definition permits, to meet the Act's explicit mandate that a credit union ''establish and maintain an office or facility *in*'' the Underserved Area it is approved to serve.[63] For the Board to depart from this statutory mandate would require Congress to amend the Act to, for example, substitute ''to serve'' for the word ''in.'' Pending such an amendment to the Act, the Board lacks the authority to adopt the recommendation to permit a transactional Web site to qualify as a valid service facility within an Underserved Area.

D. Multiple Common Bond

As amended in 1998, the Act restored the Board's multiple common bond policy, permitting a multiple common bond credit union to serve a combination of distinct, definable occupational and/or associational groups, provided each has its own common bond among group members.[64]

1. *Credit Union's ''Reasonable Proximity'' via Members' Online Access to Services.* When it is either impracticable or inconsistent with reasonable standards of safety and soundness for a group to form a stand-alone single common bond credit union, the Act requires ''inclusion of [a new] group in the [FOM] of a credit union that is within *reasonable proximity* to the location of the group whenever practicable and consistent with reasonable standards for the safe and sound operation of the credit union.''[65] Solely to meet the ''reasonable proximity'' requirement, the Board proposed revising the definition of a ''service facility'' to include online internet access in the form of a transactional Web site that gives members of added occupational or associational groups access to their credit union's products and services.[66]

[55] CFPB's annual ''Rural or underserved counties list'' does not segregate ''rural'' and ''underserved'' counties. Therefore, NCUA will use the data collected by CFPB to produce and make available a list that identifies ''underserved areas'' exclusively.

[56] *E.g.,* FDIC ''Summary of Deposits Survey,'' *supra* note 51.

[57] *E.g.,* U.S. Department of Agriculture data; Pew Research Center reports; changes in an area's characteristics between decennial Censuses; local economic factors; local poverty rates; local unemployment rate; local median family income; and reports and surveys an applicant credit union itself develops.

[58] 12 U.S.C. 2902(2)

[59] Appendix B, Ch. 2, § III.B.3.

[60] *Id.*

[61] 5 U.S.C. 706(2)(A).

[62] 12 U.S.C. 1759(c)(2).

[63] *Id.* § 1759(c)(2)(B) (emphasis added). The Board authorized video teller machines in an opinion letter dated August 6, 2012, at: *https://www.ncua.gov/regulation-supervision/Pages/rules/legal-opinions/2012/0965.aspx.*

[64] 63 FR 71998, Dec. 30, 1998; 12 U.S.C. 1759(b)(2)(A). *See NCUA* v. *First National Bank & Trust Co.,* 522 U.S. 479 (1988).

[65] 12 U.S.C. 1759(f)(1)(B) (emphasis added).

[66] The revised definition would not permit an individual to qualify remotely for membership in a

Continued

The Board noted the significant benefits of access via an electronic service facility, namely that it would put multiple common bond credit unions in parity with their depository institution competitors, and would permit them to keep pace with advances in technology that enable more efficient delivery of products and services to their members.

Scores of credit union commenters supported the proposal to modify the definition of service facility to permit use of a transactional Web site to achieve reasonable proximity between a multiple common bond credit union and members of its added groups. These commenters contented that the proposal is within the Board's authority to interpret the Act. As a practical matter, the commenters asserted that online proximity reflects the large and growing role of modern financial technology, making geographic location and physical branches less representative of the scope of a credit union's service area. Online access would allow FCUs to efficiently meet their members' needs and expectations.

Commenters stated that while an FCU's physical presence conveniently close to the groups it served may have been a practical necessity in the past, evolving technology has expanded the menu of options members have to interact with their financial institution, effectively putting them in close proximity regardless of geographic location. In contrast, scores of bank commenters opposed the proposal to amend the definition of service facility to include online access. They claimed that the proposal exceeds the Board's statutory authority and is inconsistent with Congressional intent, in that an online internet channel would ''effectively remove the statutory requirement that a multiple common bond FCU be in a 'reasonable proximity to the location of the group.'' Moreover, they criticized the proposal as inconsistent with NCUA's prior interpretation of ''reasonable proximity'' as mandating an FCU branch office or mobile office physically near the group to be added. One commenter recommended that NCUA study the effect of the proposal on the wider financial services industry.

The Board has considered the comments addressing the proposal to modify the definition of service facility to permit use of a transactional Web site to achieve ''reasonable proximity'' between a multiple common bond credit union and members of its added groups. Notwithstanding certain merits of the proposal, the Board has decided to defer action on it at this time, consistent with an incremental approach to introducing the other FOM modifications adopted in the final rule, thus permitting credit unions to acclimate to them. The Board will further study the impact of the proposal.[67] However, this decision does not detract from the Board's belief in the utility of on-line access to facilitate transactions between credit unions and their members generally.

2. *Inclusion of Select Employee Group Contractors in a Multiple Common Bond.* The proposed rule extended to *multiple* occupational common bond credit unions the ability (that single common bond credit unions already have)[68] to add persons who work regularly for an entity that is under contract to any of the SEG sponsors listed in a credit union's charter, provided there is a ''strong dependency relationship'' between the contractor and the SEG sponsor in each case.

Scores of FCU commenters supported this proposal, believing that it better reflects today's modern workforce, in which it is not uncommon for businesses to outsource work to contractors whose employees, although not directly employed by a SEG sponsor, are integral to the sponsor's functioning and operations. In some cases, the employees of an independent contractor have worked for a SEG sponsor longer than many of the sponsor's *own* employees, who were eligible for membership from the outset of their employment. As many commenters pointed out, there is no functional distinction between a single and multiple common bond credit union for purposes of recognizing the occupational common bond between a SEG sponsor's own employees and those of its contractors with whom they work.

These commenters noted that the proposal would allow greater flexibility for potential members to join an FCU, thus easing or eliminating unnecessary administrative burdens and restrictions on FCUs. As a result, they claimed that this proposal would help to expand the multiple common bond membership base nationally, thereby making affordable financial services available to more American consumers.

In contrast, bank commenters opposed the contractor eligibility proposal, arguing that it is inconsistent with the Act and its legislative history to include within a SEG the employees of its sponsor's contractors. They asserted that the Act favors the formation of single common bond credit unions.

Having considered the comments addressing inclusion of SEG contractors in a multiple common bond, the Board has determined that the proposal not only is consistent with the statute, but reflects the modern economy's increasing reliance on contractors. Specifically, the Board notes the proposal's consistency with the Act's provisions requiring a stand-alone feasibility assessment above the 3000 member threshold. The strong mutual dependency of a SEG sponsor and its contractor on each other effectively cements the single common bond the sponsor's employees and the contractor's employees share with each other.

Despite the Act's preference for the formation of single common bond credit unions, the Act expressly permits a multiple common bond addition when a group cannot reasonably establish a single common bond credit union, or likely would be unable to successfully manage and sustain such a credit union.[69] The addition of a contractor's employees to a SEG consisting of the sponsor's employees with whom they work is consistent with that approach. Accordingly, the final rule provides that a *multiple* occupational common bond credit union may add persons who work regularly for an entity that is under contract to any of the SEG sponsors listed in the credit union's charter, provided there is a ''strong dependency relationship'' between the contractor and sponsor. To extend to *multiple* common bond credit unions the ability that *single* common bond credit unions already have to add persons who work regularly for an entity under contract to its sponsor advances the Board's goal to enable parallel functioning between single and multiple common bond credit unions whenever feasible and consistent with the Act.

Some commenters requested the Board to define what constitutes a ''strong dependency relationship'' between a SEG sponsor and its contractor, but cautioned against requiring either SEG sponsors or their contractors to disclose trade secrets or confidential financial information. Some suggested permitting an FCU to pledge in good faith that it can

community credit union based on electronic access to it from outside its well-defined local community. Nor would the revised definition apply to meet the requirement that a credit union serving an Underserved Area ''must establish and maintain an office or facility in [the Underserved Area].''

[66] 12 U.S.C. 1759(c)(1)(B).

[67] The Board notes that a shared branch or other facility can be used as an alternative to meet the ''reasonable proximity'' requirement.

[68] Appendix B, Ch. 2 § II.A.1.

[69] 12 U.S.C. 1759(f)(1)(B).

document a ''strong dependency relationship'' between each SEG's sponsor and the sponsor's contractor in accordance with the particulars of the industry in which they operate. Reflecting the Board's preference for a more objective standard, the final rule defines a ''strong dependency relationship'' between a SEG sponsor and the sponsor's contractor to mean that both rely on each other as measured by a pattern of regularly doing business with each other, for example, as documented by the number, the term length and the dollar volume of prior and pending contracts between them. The Board intends the ''strong dependency'' standard to be determined by credit unions themselves, so as to create a rebuttable presumption that the sponsor's employees and those of the contractor share a single common bond, as the Act requires. NCUA's Office of Consumer Protection, or its successor, anticipates issuing further guidance to clarify what documentation will be acceptable to confirm a contractual relationship based on a pattern of regularly doing business.

3. *Multiple Common Bond of Office/Industrial Park Employees.* The existing rule expressly permits a community charter to consist of persons who are employed within an office or industrial park.[70] As an alternative to such a community charter, the proposed rule expressly permitted a multiple common bond credit union to combine in a single SEG all the employees of a park's business and retail tenants (*e.g.,* within a shopping mall, an office building or an office complex), provided each tenant has fewer than 3000 employees working regularly at a facility within the park—effectively a SEG consisting of park tenants themselves rather than their employees.

About a dozen credit union commenters specifically addressed the tenants' SEG proposal, generally favoring it as an enhancement of an FCU's ability to serve multiple businesses within an office/industrial park by leveraging its resources to provide more value to its membership. Specifically, the proposal enabled an FCU to use a park's tenant base to more efficiently identify and offer services to employees of businesses within the park.

Critics of the proposal included some credit unions and several banks that believed the proposal would create an impermissible ''hybrid'' charter that combined community and occupational common bond characteristics. Specifically, these commenters believed such a charter would make a SEG out of a group (*i.e.,* employees of a park's retail and business tenants) that is more properly characterized simply as persons who work in a geographically based community. These commenters emphasized that the Act prescribes distinct criteria for groups sharing an occupational versus an associational common bond.[71] The opponents also questioned the justification for this proposal beyond administrative convenience.

Having considered the comments addressing the tenants' SEG proposal, the Board believes it is appropriate to give the employees of a park's tenants the option to join a multiple common bond credit union. However, a SEG sponsored by a landlord and consisting of its tenants (as opposed to the landlord's *own* employees) unequivocally lacks the essential *occupational* common bond due to the lack of an employment relationship between the landlord and each tenant. Notwithstanding this structural flaw, the existing rule's language and its application in practice have convinced the Board that the rule *already* permits a park's tenants, in each one's capacity as *an employer,* to form a multiple occupational common bond credit union combining each one's individual SEG.[72]

Accordingly, in lieu of the tenant SEG proposal, the final rule clarifies the current availability of the multiple common bond option for employers within an industrial park, shopping mall, office park, or office building (each a ''park'') by expressly specifying it as an example within the rule; no rule change is required.[73] Consistent with the Act's stand-alone feasibility exemption for groups with fewer than 3000 members,[74] each park tenant's SEG must have fewer than 3000 employees who work at a facility within the park, each of whom would be eligible for FCU membership only for so long as he/she regularly works there.[75] This existing multiple common bond option creates neither a new charter type nor an impermissible hybrid community/multiple group charter; rather, it gives FCUs a choice between *either* distinct charter type to serve an office/industrial park.

4. *Streamlined Documentation to Assess Stand-Alone Feasibility of Groups of 3000 or Greater.* The proposed rule streamlined NCUA's process for assessing the stand-alone feasibility of a group of 3000 or more members (''≥3000 group'') that seeks to be added to the FOM of an existing multiple common bond credit union, instead of forming a single common bond credit union. A group of fewer than 3000 members (''<3000 group'') is subject to the existing process under the Application for Field of Membership (NCUA form 4015 EZ). A group between 3000 and 5000 is required to document its inability to form a credit union of its own based on evidence of a lack of available subsidies, disinterest among the group's members, and an overall lack of sufficient resources (NCUA form 4015–A). Groups with more than 5000 members are subject to the existing standard application process, requiring a group to fully describe its inability to establish a new single common bond credit union (NCUA form 4015). The proposed rule invited comments on whether to increase the 5000 member threshold that triggers the standard application process.

Scores of comments, both in support and in opposition, addressed the proposal to streamline the documentation requirement to assess the stand-alone feasibility of ≥3000 groups. Credit union commenters generally favored the proposal, but requested modifications, particularly to increase the membership threshold and the method of quantifying group size. Most commenters recommended increasing the threshold to 5000, while others recommended increasing it to as many as 20,000 members. One commenter recommended eliminating a numerical threshold completely. Further, many credit union commenters recommended evaluating the stand-alone feasibility criteria using the number of actual rather than potential members. Acknowledging the Board's initial rationale for the streamlined approach—that 80 percent of failures occur among FCUs with fewer than

[70] Appendix B, ch. 2 § V.A.7.

[71] As set forth in the Chartering Manual, the criteria of an occupational common bond are: (1) Employment in a single corporation, (2) employment in a corporation with a controlling interest in or by another legal entity, (3) employment in a corporation which is related to another legal entity (such as a company under contract and possessing a strong dependency relationship with another company); (4) employment or attendance in a school, or (5) employment in the same Trade, Industry or Profession. Appendix B, ch. 2, § II.A.1.

[72] Appendix B, ch. 1 § XI.

[73] To facilitate the formation of multiple SEGs among a park's retail and business tenants, a multiple common bond credit union could rely on a letter from an authorized representative of the park, such as its leasing agent, to identify each incoming tenant capable of forming its own SEG, and to give notice of the departure of an existing SEG's sponsor from the park, thus discontinuing its SEG.

[74] 12 U.S.C. 1759(d)(2)(A).

[75] Appendix B, ch. 2, § IV.A.1.

5000 actual members [76]—certain supporters urged NCUA to consider the safety and soundness consequences and the risk to the Insurance Fund of insisting that groups between 3000 and 5000 members form their own credit unions. They suggested that NCUA's goal should be to charter FCUs that are most likely to survive.

Several bank commenters criticized the proposal, claiming that it violates the Act and is inconsistent with the legislative history. These commenters stated that, with limited exceptions, the Act expressly limits to 3000 members the size of a group that can be added to an existing multiple common bond credit union. The commenters were concerned that the proposal's practical effect would be to unilaterally increase the numerical limitation prescribed by law.

In contrast, credit union commenters insisted that the proposal is within the Act's statutory authority because it does not obviate the requirement that a >3000 group demonstrate its inability to establish a new single common bond FCU. In their view, it allows NCUA to accept a group's statement of inability to form a stand-alone credit union in lieu of full supporting documentation. To the extent such documentation is absent, they noted that NCUA retains the ability to reject or to further investigate a group's statement of inability to form a stand-alone credit union.

Having considered the comments addressing the streamlined documentation proposal for assessing the stand-alone feasibility of >3000 groups, it is clear that commenters opposing the proposal relied on a fundamental misconception—that the proposal would alter the 3000 member stand-alone feasibility threshold mandated by the Act. On the contrary, the final rule merely reduces the documentation required, depending on group size, to support a stand-alone feasibility determination, while continuing to honor both the 3000 member feasibility threshold and the feasibility criteria that the Act prescribes. Further, streamlining the required documentation is a response to complaints to the agency from multiple common bond credit unions that the excessive paperwork demand on groups they seek to add has been a disincentive to those groups, causing them to withdraw in frustration.

Certain credit unions urged the Board to increase the threshold above 5000, if based on potential members or, if left at 5000, to base it on actual members. These commenters did not provide a compelling justification for adjusting this amount at this time. On the contrary, the Board has determined that the proposed 5000 member threshold is appropriate at this time, believing that it represents the minimum number of potential members needed for a credit union to maintain long-term economic viability.

The process of applying the statutory stand-alone feasibility criteria is identical under both the streamlined documentation and the standard approaches. In either case, the Board would review a >3000 group's application and determine whether to accept or reject it, or to request additional supporting information. Accordingly, the streamlined documentation proposal is consistent with the Act's stand-alone feasibility mandate.

5. *Commenter-initiated Emergency Merger Proposal.* To facilitate mergers between credit unions with unlike common bonds, several commenters recommended a variety of approaches for relaxing, if not effectively disregarding, the statutory standard authorizing an emergency merger free of the FOM constraints the Act otherwise imposes. ''Notwithstanding any other provision of law,'' including the FOM limitations it may impose, the Act permits the Board to authorize the merger of an insured credit union (or a purchase and assumption of its assets) provided the credit union is ''insolvent or is in danger of insolvency.'' [77] Given that this explicit, objectively measurable ''insolvency'' standard is expressly imposed by the Act, the Board is bound by it no matter what other circumstances it would consider to warrant a merger of unlike common bonds. Within that standard, the Board retains discretion to define ''danger of insolvency,'' *e.g.,* in terms of imminence, as the existing rule does according to time increments (between 12 and 36 months) pending a credit union's declining net worth classification.[78] The Board will, in a separate rulemaking, consider alternative approaches to define the ''danger of insolvency'' prerequisite for an emergency merger of unlike common bonds.

E. Other Persons Eligible for Credit Union Membership

NCUA has historically recognized a variety of persons who, by virtue of their relationship to a common bond group, have been entitled to credit union membership eligibility.[79] To recognize the contributions of those who have served in the United States Armed Forces, and to give them the benefit of access to credit union service following active duty, the proposed rule permitted a credit union to include as an affinity group within its common bond the honorably discharged veterans of any branch of the United States Armed Forces listed in its charter.

Credit union commenters uniformly favored this proposal for recognizing not only the affinity that veterans share with their own active duty branch of service, but the affinity among active duty and retired military personnel generally. Some commenters supported the proposal as a means to protect military veterans from unscrupulous lenders. Another opposed it as too expansive, contending that it would justify membership eligibility for retirees of other organizations within an FOM. Conversely, yet another commenter advocated expanding the proposal to grant membership eligibility based upon the affinity of, for example, retired federal employees and retired teachers. The single bank commenter who addressed this proposal was concerned that it would enable individuals to use ''creative measures'' to join an FCU by group affinity generally.

Having considered the comments addressing the proposal to extend membership eligibility to honorably discharged military members, the Board believes that it is appropriate due to the unique bond that discharged veterans typically retain with their former branch of service (*e.g.,* via military-sponsored morale, welfare and recreational associations). The Board emphasizes that such an affinity applies exclusively to honorably discharged veterans; in contrast, membership eligibility would be available to retirees of other groups, such as teachers or federal employees within an FOM, only to the extent an individual credit union permits it in its charter. Accordingly, exclusively for ''Honorably discharged veterans who served in any of the Armed Services of the United States listed in [a credit union's] charter,'' the final rule automatically grants membership eligibility.[80]

[76] 80 FR at 76754.

[77] 12 U.S.C. 1785(h).

[78] Appendix B, Ch. 2, section II.D.2. (glossary definition of ''danger of insolvency'').

[79] Appendix B, Ch.2, sections II.H., IV.H., and Appendix 1 (glossary definition of ''affinity'').

[80] Appendix B, Ch. 2, § II.H.

F. Inclusion of ''Strong Dependency'' Vendors and Suppliers in a Single Common Bond Within a Trade, Industry or Profession

A single occupational common bond within a trade, industry or profession (a ''TIP'') is based on employment by any number of separately owned corporations or other legal entities that share a common bond by reason of producing similar products, providing similar services, sharing the same profession or trade, or participating in the same industry.[81] A TIP-based common bond requires a narrow commonality of interests among the TIP entities' employees and a close nexus among the entities themselves.[82]

The proposed rule clarified that the existing definition of a TIP-based single common bond of occupation includes employees of entities that have a strong dependency relationship on, and whose employees work directly with employees of, other entities within the same industry, to the extent that a significant, if not equal, economic impact is likely if one were unable to continue in its operations without doing business with the other.

Several credit unions favored the proposal to include ''strong dependency'' vendors and suppliers in a TIP, stating that it would provide regulatory relief in allowing TIP credit unions to reach potential members more easily. One commenter welcomed the Board's recognition that current employment practices frequently involve outsourcing of work to independent vendors and suppliers under contract. No commenter opposed the proposal.

Some commenters expressed a mistaken belief that the existing rule restricts a TIP charter from serving the entire nation. On the contrary, the existing rule imposes no geographic limitation on service to the groups within a TIP. In fact, NCUA has approved several TIPs whose groups span the whole nation.

Having considered the comments addressing the proposal to include ''strong dependency'' vendors and suppliers in a TIP, the Board has decided to adopt it in the final rule.[83] Further, at the request of commenters, the final rule defines a ''strong dependency'' relationship between TIP entities and their vendors and suppliers as a relationship in which they rely on each other to the extent, for example, that the absence of one likely would cause the other to suffer a material decline in either revenue, functionality or productivity, among other consequences.[84]

G. Technical Updates

Since publishing the December 2015 proposed rule, the Board has renamed the agency's Office of Consumer Protection as the Office of Consumer Financial Protection and Access (''OCFPA''). Accordingly, the final rule updates the agency's Chartering Manual to substitute OCFPA in place of certain references to regional office and regional director chartering responsibilities, and to substitute the Board Secretary for the former Office of Consumer Protection in reference to appeals of chartering decisions.[85] The final rule also corrects statutory and regulatory citations and cross-references in the Chartering Manual and its appendices, and updates those appendices to reflect current information and practices.

III. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a regulation may have on a substantial number of small entities.[86] For purposes of this analysis, NCUA considers small credit unions to be those having under $100 million in assets.[87] This rule is anticipated to economically benefit FCUs that choose to expand their FOMs, but not to the extent that it will affect a substantial number of small entities. In any case, NCUA certifies that the rule will not have a significant economic impact on small credit unions.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'')[88] applies to collections of information through which an agency creates a paperwork burden on regulated entities or the public, or revises existing burden.[89] For purposes of the PRA, a paperwork burden may take the form of either a reporting, recordkeeping, or third-party disclosure requirement, also referred to as information collections.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number. This rule involves a collection of information approved under OMB control number 3133–0015—Chartering and Field of Membership Manual.

The final rule creates new strategic options for FCUs, while requiring of them essentially the same information that the existing rule required to apply for and be granted a charter expansion or conversion, with two exceptions. It introduces a new form (NCUA 4015–A) within Appendix 4 to the Chartering and Field of Membership Manual that condenses the application process that otherwise would apply to the addition of certain groups to a multiple common bond FOM. Using this condensed version will streamline the application process and will no longer require completion of the Form 4015. By adding this option, no new burden is realized with the addition of NCUA 4015–A.

Regarding a community common bond, the final rule permits a community FCU to add an area adjacent to the perimeter of an existing community consisting of a Single Political Jurisdiction, Core Based Statistical Area or Combined Statistical Area, based upon a narrative showing that residents on both sides of the perimeter interact or share common interests. For that purpose, the rule identifies compelling indicia of interaction or common interests that would be relevant in developing and supporting a narrative to establish that the residents of the expanded community meet the requirements of a well-defined local community.

NCUA has determined that the procedure for an FCU to assemble such evidence of interaction or common interests, and to develop and submit a narrative summarizing the evidence to support its application to expand, would create a new information collection requirement. In the proposed rule, NCUA identified and described this new information collection requirement, estimating the time it would take to comply, and solicited commenters on the information collection aspects of the proposed rule. The sole commenter who addressed the information collection aspects of the proposed rule concluded without explanation that it would double the existing paperwork burden. The burden outlined in the December proposed rule revealed an increase of 26,160 hours due to the new and revised information collection requirements. With this estimated increase, the total burden

[81] 68 FR 18334, 18336 (April 15, 2003); Appendix B, ch. 2, § IIA.2.

[82] *Id.*

[83] Appendix B, Ch. 2, section II.A.2.

[84] *Id.*

[85] Appendix B, Ch. 2, sections II.C., II.C.6., III.C., III.C.6., IV.B., IV.B.5., V.C. and VII.D.

[86] 5 U.S.C. 603(a).

[87] *See* 80 FR 57512 (Sept. 24, 2015).

[88] 44 U.S.C. 3501 *et seq.*

[89] *Id.* § 3507(d); 5 CFR part 1320.

requested under OMB No. 3133–0015 is 44,223 hours.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. To adhere to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive Order. Primarily because this rule applies to FCUs exclusively, it will not have a substantial direct effect on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined this rule does not constitute a policy that has federalism implications for purposes of the Executive Order 13132.

Assessment of Federal Regulations and Policies on Families

NCUA has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[90]

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (''SBREFA'') provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the Administrative Procedure Act.[91] NCUA does not believe this final rule is a ''major rule'' within the meaning of the relevant sections of SBREFA, but as required, has submitted this final rule to OMB for its determination.

List of Subjects in 12 CFR Part 701

Credit, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on October 27, 2016.

Gerard S. Poliquin,

Secretary of the Board.

For the reasons stated above, NCUA amends 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

■ 1. The authority for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1786, 1787, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.;* 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

■ 2. Appendix B to part 701 is revised to read as follows:

Appendix B to Part 701—Chartering and Field of Membership Manual

Chapter 1 — Federal Credit Union Chartering

I—Goals of NCUA Chartering Policy

The National Credit Union Administration's (NCUA) chartering and field of membership policies are directed toward achieving the following goals:

- To encourage the formation of credit unions;
- To uphold the provisions of the Federal Credit Union Act;[92]
- To promote thrift and credit extension;
- To promote credit union safety and soundness; and
- To make quality credit union service available to all eligible persons.

NCUA may grant a charter to single occupational/associational groups, multiple groups, or communities if:

- The occupational, associational, or multiple groups possess an appropriate common bond or the community represents a well-defined local community, neighborhood, or rural district;
- The subscribers are of good character and are fit to represent the proposed credit union; and
- The establishment of the credit union is economically advisable.

Generally, these are the primary criteria that NCUA will consider. In unusual circumstances, however, NCUA may examine other factors, such as other federal law or public policy, in deciding if a charter should be approved.

Unless otherwise noted, the policies outlined in this manual apply only to federal credit unions.

II—Types of Charters

The Federal Credit Union Act recognizes three types of federal credit union charters—single common bond (occupational and associational), multiple common bond (more than one group each having a common bond of occupation or association), and community.

The requirements that must be met to charter a federal credit union are described in Chapter 2. Special rules for credit unions serving low-income groups are described in Chapter 3.

If a federal credit union charter is granted, Section 5 of the charter will describe the credit union's field of membership, which defines those persons and entities eligible for membership. Generally, federal credit unions are only able to grant loans and provide services to persons within the field of membership who have become members of the credit union.

III—Subscribers

Federal credit unions are generally organized by persons who volunteer their time and resources and are responsible for determining the interest, commitment, and economic advisability of forming a federal credit union. The organization of a successful federal credit union takes considerable planning and dedication.

Persons interested in organizing a federal credit union should contact one of the credit union trade associations or the NCUA regional office serving the state in which the credit union will be organized. Lists of NCUA offices and credit union trade associations are shown in the appendices. NCUA will provide information to groups interested in pursuing a federal charter and will assist them in contacting an organizer.

While anyone may organize a credit union, a person with training and experience in chartering new federal credit unions is generally the most effective organizer. However, extensive involvement by the group desiring credit union service is essential.

The functions of the organizer are to provide direction, guidance, and advice on the chartering process. The organizer also provides the group with information about a credit union's functions and purpose as well as technical assistance in preparing and submitting the charter application. Close communication and cooperation between the organizer and the proposed members are critical to the chartering process.

The Federal Credit Union Act requires that seven or more natural persons—the ''subscribers''—present to NCUA for approval a sworn organization certificate stating at a minimum:

- The name of the proposed federal credit union;
- The location of the proposed federal credit union and the territory in which it will operate;
- The names and addresses of the subscribers to the certificate and the number of shares subscribed by each;
- The initial par value of the shares;
- The detailed proposed field of membership; and
-
- The fact that the certificate is made to enable such persons to avail themselves of the advantages of the Federal Credit Union Act.

Willfully and knowingly making false statements on any of the required documentation filed in obtaining a federal credit union charter may be grounds for federal criminal prosecution under 18 U.S.C. 1001.

IV—Economic Advisability

IV.A—General

Before chartering a federal credit union, NCUA must be satisfied that the institution will be viable and that it will provide needed services to its members. Economic advisability, which is a key factor in determining whether a potential charter will have a reasonable opportunity to succeed, is

[90] Public Law 105–277, 112 Stat. 2681 (1998).

[91] 5 U.S.C. 551.

[92] 12 U.S.C. 1751 *et seq.*

essential in order to qualify for a credit union charter.

NCUA will conduct an independent on-site investigation of each charter application to ensure that the proposed credit union can be successful. In general, the success of any credit union depends on: (a) The character and fitness of management; (b) the depth of the members' support; and (c) present and projected market conditions.

IV.B—Proposed Management's Character and Fitness

The Federal Credit Union Act requires NCUA to ensure that the subscribers are of good ''general character and fitness.'' Prospective officials and employees will be the subject of credit and background investigations. The investigation report must demonstrate each applicant's ability to effectively handle financial matters. Employees and officials should also be competent, experienced, honest and of good character. Factors that may lead to disapproval of a prospective official or employee include criminal convictions, indictments, and acts of fraud and dishonesty. Further, factors such as serious or unresolved past due credit obligations and bankruptcies disclosed during credit checks may disqualify an individual.

NCUA also needs reasonable assurance that the management team will have the requisite skills—particularly in leadership and accounting—and the commitment to dedicate the time and effort needed to make the proposed federal credit union a success.

Section 701.14 of NCUA's Rules and Regulations sets forth the procedures for NCUA approval of officials of newly chartered credit unions. If the application of a prospective official or employee to serve is not acceptable to the Office of Consumer Financial Protection and Access Director, the group can propose an alternate to act in that individual's place. If the charter applicant feels it is essential that the disqualified individual be retained, the individual may appeal the Office of Consumer Financial Protection and Access Director's decision to the NCUA Board. If an appeal is pursued, action on the application may be delayed. If the appeal is denied by the NCUA Board, an acceptable new applicant must be provided before the charter can be approved.

IV.C—Member Support

Economic advisability is a major factor in determining whether the credit union will be chartered. An important consideration is the degree of support from the field of membership. The charter applicant must be able to demonstrate that membership support is sufficient to ensure viability.

NCUA has not set a minimum field of membership size for chartering a federal credit union. Consequently, groups of any size may apply for a credit union charter and be approved if they demonstrate economic advisability. However, it is important to note that often the size of the group is indicative of the potential for success. For that reason, a charter application with fewer than 3,000 primary potential members (*e.g.,* employees of a corporation or members of an association) may not be economically advisable. Therefore, a charter applicant with a proposed field of membership of fewer than 3,000 primary potential members may have to provide more support than an applicant with a larger field of membership. For example, a small occupational or associational group may be required to demonstrate a commitment for long-term support from the sponsor.

IV.D—Present and Future Market Conditions—Business Plan

The ability to provide effective service to members, to compete in the marketplace, and to adapt to changing market conditions are key to the survival of any enterprise. Before NCUA will charter a credit union, a business plan based on realistic and supportable projections and assumptions must be submitted.

The business plan should contain, at a minimum, the following elements:

- Mission statement;
- Analysis of market conditions, including if applicable, geographic, demographic, employment, income, housing, and other economic data;
- Evidence of member support;
- Goals for shares, loans, and for number of members;
- Financial services needed/desired;
- Financial services to be provided to members of all segments within the field of membership;
- How/when services are to be implemented;
- Organizational/management plan addressing qualification and planned training of officials/employees;
- Continuity plan for directors, committee members and management staff;
-
- Operating facilities, to include office space/equipment and supplies, safeguarding of assets, insurance coverage, etc.;
- Type of record-keeping and data processing system;
- Detailed semiannual pro forma financial statements (balance sheet, income and expense projections) for 1st and 2nd year, including assumptions—*e.g.,* loan and dividend rates;
- Plans for operating independently;
- Written policies (shares, lending, investments, funds management, capital accumulation, dividends, collections, etc.);
- Source of funds to pay expenses during initial months of operation, including any subsidies, assistance, etc., and terms or conditions of such resources; and
- Evidence of sponsor commitment (or other source of support) if subsidies are critical to success of the federal credit union. Evidence may be in the form of letters, contracts, financial statements from the sponsor, and any other such document on which the proposed federal credit union can substantiate its projections.

While the business plan may be prepared with outside assistance, the subscribers and proposed officials must understand and support the submitted business plan.

V—Steps in Organizing a Federal Credit Union

V.A—Getting Started

Following the guidance contained throughout this policy, the organizers should submit wording for the proposed field of membership (the persons, organizations and other legal entities the credit union will serve) to NCUA early in the application process for written preliminary approval. The proposed field of membership must meet all common bond or community requirements.

Once the field of membership has been given preliminary approval, the organizer should conduct an organizational meeting to elect seven to ten persons to serve as subscribers. The subscribers should locate willing individuals capable of serving on the board of directors, credit committee, supervisory committee, and as chief operating officer/manager of the proposed credit union.

Subsequent organizational meetings may be held to discuss the progress of the charter investigation, to announce the proposed slate of officials, and to respond to any questions posed at these meetings.

If NCUA approves the charter application, the subscribers, as their final duty, will elect the board of directors of the proposed federal credit union. The new board of directors will then appoint the supervisory committee.

V. B—Charter Application Documentation

V.B.1—General

As discussed previously in this Chapter, the organizer of a federal credit union charter must, at a minimum, provide evidence that:

- The group(s) possess an appropriate common bond or the geographical area to be served is a well-defined local community, neighborhood, or rural district;
- The subscribers, prospective officials, and employees are of good character and fitness; and
- The establishment of the credit union is economically advisable.

As part of the application process, the organizer must submit the following forms, which are available in appendix 4 of this Manual:

- Federal Credit Union Investigation Report, NCUA 4001;
- Organization Certificate, NCUA 4008;
-
- Report of Official and Agreement To Serve, NCUA 4012;
- Application and Agreements for Insurance of Accounts, NCUA 9500; and
- Certification of Resolutions, NCUA 9501.

Each of these forms is described in more detail in the following sections.

V.B.2—Federal Credit Union Investigation Report, NCUA 4001

The application for a new federal credit union will be submitted on NCUA 4001. State-chartered credit unions applying for conversion to a federal charter will use NCUA 4000. (See Chapter 4 for a full discussion.) The organizer is required to certify the information and recommend approval or disapproval, based on the investigation of the request.

V.B.3—Organization Certificate, NCUA 4008

This document, which must be completed by the subscribers, includes the seven criteria established by the Federal Credit Union Act. NCUA staff assigned to the case will assist in the proper completion of this document.

V.B.4—Report of Official and Agreement To Serve, NCUA 4012

This form documents general background information of each official and employee of the proposed federal credit union. Each official and employee must complete and sign this form. The organizer must review each of the NCUA 4012s for elements that would prevent the prospective official or employee from serving. Further, such factors as serious, unresolved past due credit obligations and bankruptcies disclosed during credit checks may disqualify an individual.

V.B.5—Application and Agreements for Insurance of Accounts, NCUA 9500

This document contains the agreements with which federal credit unions must comply in order to obtain National Credit Union Share Insurance Fund (NCUSIF) coverage of member accounts. The document must be completed and signed by both the chief executive officer and chief financial officer. A federal credit union must qualify for federal share insurance.

V.B. 5—Certification of Resolutions, NCUA 9501

This document certifies that the board of directors of the proposed federal credit union has resolved to apply for NCUSIF insurance of member accounts and has authorized the chief executive officer and recording officer to execute the Application and Agreements for Insurance of Accounts. Both the chief executive officer and recording officer of the proposed federal credit union must sign this form.

VI—Name Selection

It is the responsibility of the federal credit union organizers or officials of an existing credit union to ensure that the proposed federal credit union name or federal credit union name change does not constitute an infringement on the name of any corporation in its trade area. This responsibility also includes researching any service marks or trademarks used by any other corporation (including credit unions) in its trade area. NCUA will ensure, to the extent possible, that the credit union's name:

- Is not already being officially used by another federal credit union;
- Will not be confused with NCUA or another federal or state agency, or with another credit union; and
- Does not include misleading or inappropriate language.

The last three words in the name of every credit union chartered by NCUA must be ''Federal Credit Union.''

The word ''community,'' while not required, can only be included in the name of federal credit unions that have been granted a community charter.

VII—NCUA Review

VII.A—General

Once NCUA receives a complete charter application package, an acknowledgment of receipt will be sent to the organizer. During the review process, a staff member will be assigned to perform an on-site contact with the proposed officials and others having an interest in the proposed federal credit union.

NCUA staff will review the application package and verify its accuracy and reasonableness. A staff member will inquire into the financial management experience and the suitability and commitment of the proposed officials and employees, and will make an assessment of economic advisability. The staff member will also provide guidance to the subscribers in the proper completion of the Organization Certificate, NCUA 4008.

Credit and background investigations may be conducted concurrently by NCUA with other work being performed by the organizer and subscribers to reduce the likelihood of delays in the chartering process.

The staff member will analyze the prospective credit union's business plan for realistic projections, attainable goals, adequate service to all segments of the field of membership, sufficient start-up capital, and time commitment by the proposed officials and employees. Any concerns will be reviewed with the organizer and discussed with the prospective credit union's officials. Additional on-site contacts by NCUA staff may be necessary. The organizer and subscribers will be expected to take the steps necessary to resolve any issues or concerns. Such resolution efforts may delay processing the application.

NCUA staff will then make a recommendation to the Office of Consumer Financial Protection and Access Director regarding the charter application. The recommendation may include specific provisions to be included in a Letter of Understanding and Agreement. In most cases, NCUA will require the prospective officials to adhere to certain operational guidelines. Generally, the agreement is for a limited term of two to four years. A sample Letter of Understanding and Agreement is found in appendix 2.

VII.B—Office of Consumer Financial Protection and Access Director Approval

Once approved, the board of directors of the newly formed federal credit union will receive a signed charter and standard bylaws from the Office of Consumer Financial Protection and Access Director. Additionally, the officials will be advised of the name of the examiner assigned responsibility for supervising and examining the credit union.

VII.C—Office of Consumer Financial Protection and Access Director Disapproval

When the Office of Consumer Financial Protection and Access Director disapproves any charter application, in whole or in part, the organizer will be informed in writing of the specific reasons for the disapproval. Where applicable, the Office of Consumer Financial Protection and Access Director will provide information concerning options or suggestions that the applicant could consider for gaining approval or otherwise acquiring credit union service. The letter of denial will include the procedures for appealing the decision.

VII.D—Appeal of Office of Consumer Financial Protection and Access Director Decision

If the Office of Consumer Financial Protection and Access Director denies a charter application, in whole or in part, that decision may be appealed to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial and must address the specific reasons for denial. The appeal must be clearly identified as such and address the specific reason(s) the prospective group disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access Director. NCUA central office staff will make an independent review of the facts and present the appeal with a recommendation to the NCUA Board.

Before appealing, the prospective group may, within 30 days of the denial, provide supplemental information to the Office of Consumer Financial Protection and Access Director for reconsideration. A reconsideration will contain new and material evidence addressing the reasons for the initial denial. The Office of Consumer Financial Protection and Access Director will have 30 days from the date of the receipt of the request for reconsideration to make a final decision. If the request is again denied, the applicant may proceed with the appeal process within 60 days of the date of the last denial. A second request for reconsideration will be treated as an appeal to the NCUA Board.

VII.E—Commencement of Operations

Assistance in commencing operations is generally available through the various credit union trade organizations listed in appendix 5.

All new federal credit unions are also encouraged to establish a mentor relationship with a knowledgeable, experienced credit union individual or an existing, well-operated credit union. The mentor should provide guidance and assistance to the new credit union through attendance at meetings and general oversight. Upon request, NCUA will provide assistance in finding a qualified mentor.

VIII—Future Supervision

Each federal credit union will be examined regularly by NCUA to determine that it remains in compliance with applicable laws and regulations and to determine that it does not pose undue risk to the NCUSIF. The examiner will contact the credit union officials shortly after approval of the charter in order to arrange for the initial examination (usually within the first six months of operation).

The examiner will be responsible for monitoring the progress of the credit union and providing the necessary advice and guidance to ensure it is in compliance with applicable laws and regulations. The examiner will also monitor compliance with the terms of any required Letter of

Understanding and Agreement. Typically, the examiner will require the credit union to submit copies of monthly board minutes and financial statements.

The Federal Credit Union Act requires all newly chartered credit unions, up to two years after the charter anniversary date, to obtain NCUA approval prior to appointment of any new board member, credit or supervisory committee member, or senior executive officer. Section 701.14 of the NCUA Rules and Regulations sets forth the notice and application requirements. If NCUA issues a Notice of Disapproval, the newly chartered credit union is prohibited from making the change.

NCUA may disapprove an individual serving as a director, committee member or senior executive officer if it finds that the competence, experience, character, or integrity of the individual indicates it would not be in the best interests of the members of the credit union or of the public to permit the individual to be employed by or associated with the credit union. If a Notice of Disapproval is issued, the credit union may appeal the decision to the NCUA Board.

IX—Corporate Federal Credit Unions

A corporate federal credit union is one that is operated primarily for the purpose of serving other credit unions. Corporate federal credit unions are not governed by this manual, but instead operate under and are administered by the NCUA Office of National Examinations and Supervision.

X—Groups Seeking Credit Union Service

NCUA will attempt to assist any group in chartering a credit union or joining an existing credit union. If the group is not eligible for federal credit union service, NCUA will refer the group to the appropriate state supervisory authority where different requirements may apply.

XI—Field of Membership Designations

NCUA will designate a credit union based on the following criteria:

Single Occupational: If a credit union serves a single occupational sponsor, such as ABC Corporation, it will be designated as an occupational credit union. A single occupational common bond credit union may also serve a trade, industry, or profession (TIP), such as all teachers.

Single Associational: If a credit union serves a single associational sponsor, such as the Knights of Columbus, it will be designated as an associational credit union.

Multiple Common Bond: If a credit union serves more than one group, each of which has a common bond of occupation and/or association, it will be designated as a multiple common bond credit union.

Community: All community credit unions will be designated as such, followed by a description of their geographic boundaries, including but not limited to city or county boundaries, roadways, rivers, transportation lines.

Credit unions desiring to confirm or submit an application to change their designations should contact the Office of Consumer Financial Protection and Access.

XII—Foreign Branching

A federal credit union is permitted to serve foreign nationals within its field of membership wherever such individuals reside if management has the ability and resources to serve them. Before a credit union opens a branch outside the United States, it must submit an application to do so and have prior written approval of the regional director or Office of National Examinations and Supervision Director. A federal credit union may establish a service facility on a United States military installation or United States embassy without prior NCUA approval.

Chapter 2 — Field of Membership Requirements for Federal Credit Unions

I—Introduction

I.A.1—General

As set forth in Chapter 1, the Federal Credit Union Act provides for three types of federal credit union charters—single common bond (occupational or associational), multiple common bond (multiple groups), and community. Section 109 (12 U.S.C. 1759) of the Federal Credit Union Act addresses the membership requirements for each type of charter.

The field of membership, which is specified in Section 5 of the charter, defines those persons and entities eligible for membership. A single common bond federal credit union consists of one group having a common bond of occupation or association. A multiple common bond federal credit union consists of more than one group, each of which has a common bond of occupation or association. A community federal credit union consists of persons or organizations within a well-defined local community, neighborhood, or rural district.

Once chartered, a federal credit union can amend its field of membership; however, the same common bond or community requirements for chartering the credit union must be satisfied. Since there are differences in the three types of charters, special rules apply to each, which are fully discussed in the following sections of this Chapter.

I.A. 2—Special Low-Income Rules

Generally, federal credit unions can only grant loans and provide services to persons who have joined the credit union. The Federal Credit Union Act states that one of the purposes of federal credit unions is ''to serve the productive and provident credit needs of individuals of modest means.'' Although field of membership requirements are applicable, special rules set forth in Chapter 3 may apply to low-income designated credit unions and those credit unions assisting low-income groups or to a federal credit union that adds an underserved community to its field of membership.

II—Occupational Common Bond

II.A.1—General

A single occupational common bond federal credit union may include in its field of membership all persons and entities who share that common bond. NCUA permits a person's membership eligibility in a single occupational common bond group to be established in five ways:

- Employment (or a contractual relationship equivalent to employment) in a single corporation or other legal entity makes that person part of a single occupational common bond;
- Employment in a corporation or other legal entity with a controlling ownership interest (which shall not be less than 10 percent) in or by another legal entity makes that person part of a single occupational common bond;
- Employment in a corporation or other legal entity which is related to another legal entity (such as a company under contract and possessing a strong dependency relationship with another company) makes that person part of a single occupational common bond;
- Employment or attendance at a school makes that person part of a single occupational common bond (see Chapter 2, Section III.A.1); or
- Employment in the same Trade, Industry, or Profession (TIP) (see Chapter 2, Section II.A.2).

A geographic limitation is not a requirement for a single occupational common bond. However, for purposes of describing the field of membership, the geographic areas being served may be included in the charter. For example:

- Employees, officials, and persons who work regularly under contract in Miami, Florida for ABC Corporation and subsidiaries;
- Employees of ABC Corporation who are paid from * * *;
- Employees of ABC Corporation who are supervised from * * *;
- Employees of ABC Corporation who are headquartered in * * *; and/or
- Employees of ABC Corporation who work in the United States.

The corporation or other legal entity (*i.e.,* the employer) may also be included in the common bond—*e.g.,* ''ABC Corporation.'' The corporation or legal entity will be defined in the last clause in Section 5 of the credit union's charter.

A charter applicant must provide documentation to establish that the single occupational common bond requirement has been met.

Some examples of valid single occupational common bonds are:

- Employees of the Hunt Manufacturing Company who work in West Chester, Pennsylvania. (common bond—same employer with geographic definition);
- Employees of the Buffalo Manufacturing Company who work in the United States. (common bond—same employer with geographic definition);
- Employees, elected and appointed officials of municipal government in Parma, Ohio. (common bond—same employer with geographic definition);
- Employees of Johnson Soap Company and its majority owned subsidiary, Johnson Toothpaste Company, who work in, are paid from, are supervised from, or are headquartered in Augusta and Portland, Maine. (common bond—parent and subsidiary company with geographic definition);
-
- Employees of MMLLJS contractor who work regularly at the U.S. Naval Shipyard in

Bremerton, Washington. (common bond—employees of contractors with geographic definition);

• Employees, doctors, medical staff, technicians, medical and nursing students who work in or are paid from the Newport Beach Medical Center, Newport Beach, California. (single corporation with geographic definition);

• Employees of JLS, Incorporated and MJM, Incorporated working for the LKM Joint Venture Company in Catalina Island, California. (common bond—same employer—ongoing dependent relationship);

• Employees of and students attending Georgetown University. (common bond—same occupation);

• Employees of all the schools supervised by the Timbrook Board of Education in Timbrook, Georgia. (common bond—same employer); or

• All licensed nurses in Fairfax County, Virginia. (occupational common bond TIP).

In contrast, some examples of insufficiently defined single occupational common bonds are:

• Employees of manufacturing firms in Seattle, Washington. (no defined occupational sponsor; overly broad TIP);

• Persons employed or working in Chicago, Illinois. (no occupational common bond).

II.A. 2—Trade, Industry, or Profession

A common bond based on employment in a trade, industry, or profession can include employment at any number of corporations or other legal entities that—while not under common ownership—have a common bond by virtue of producing similar products, providing similar services, or participating in the same type of business.

While proposed or existing single common bond credit unions have some latitude in defining a trade, industry, or profession occupational common bond, it cannot be defined so broadly as to include groups in fields which are not closely related. For example, the manufacturing industry, energy industry, communications industry, retail industry, or entertainment industry would not qualify as a TIP because each industry lacks the necessary commonality. However, textile workers, realtors, nurses, teachers, police officers, or U.S. military personnel are closely related and each would qualify as a TIP.

The common bond relationship must be one that demonstrates a narrow commonality of interests within a specific trade, industry, or profession. If a credit union wants to serve a physician TIP, it can serve all physicians, but that does not mean it can also serve all clerical staff in the physicians' offices. However, if the TIP is based on the health care industry, then clerical staff would be able to be served by the credit union because they work in the same industry and have the same commonality of interests.

If a credit union wants to include the airline services industry, it can serve airline and airport personnel but not passengers. Clients or customers of the TIP are not eligible for credit union membership (*e.g.,* patients in hospitals). Any company that is involved in more than one industry cannot be included in an industry TIP (*e.g.,* a company that makes tobacco products, food products, and electronics). However, employees of these companies may be eligible for membership in a variety of trade/profession occupational common bond TIPs.

Although a TIP should be narrowly defined, and ordinarily would not include third-party vendors and other suppliers, it may include, on a case by case basis, employees of types of entities that have a ''strong dependency relationship'' and work directly with other types of entities within the industry. In this context, a ''strong dependency relationship'' between a TIP entity and its supplier/vendor must be demonstrated by their reliance on each other as measured by the presence of indicators of a likelihood that the absence of one would cause the other to suffer a material decline in either revenue, functionality or productivity.

Under this definition, a firm whose employees are specially trained to protect nuclear facilities, and whose employees work primarily at such facilities, could be a part of a TIP based on the firm's participation in the nuclear energy industry.

Other ''strong relationship'' indicators NCUA would consider include the regularity or frequency of work that employees of the entity perform at facilities directly related to the industry, or the degree to which employees must adjust their work practices to adapt to the needs of the industry. For example, a company's focus on producing specialized confectionary products for a hotel chain could add that company to a hospitality industry TIP. A credit union seeking to include a clause of this type in its TIP charter must provide a brief narrative identifying indicators that support the existence of a strong dependency relationship between the TIP entity and its individual supplier/vendors.

Likewise, an FCU may serve employees of companies within the commercial airline industry that have a strong dependency relationship with airlines or airports, without the limitation that these employees work at an airport. However, these employees must work directly with the following: Air transportation of freight, air courier services; air passenger services; airport baggage handling; airport security; commercial airport janitorial services; maintenance, servicing, and repair services; and on board airline food services. The employees of those entities have a narrow commonality of interests, share the single occupational common bond, and can be included within the Air Transportation Industry field of membership.

In general, except for credit unions serving a national field of membership or operating in multiple states, a geographic limitation is required for a TIP credit union. The geographic limitation will be part of the credit union's charter and generally correspond to its current or planned operational area. More than one federal credit union may serve the same trade, industry, or profession, even if both credit unions are in the same geographic location.

This type of occupational common bond is only available to single common bond credit unions. A TIP cannot be added to a multiple common bond or community field of membership.

To obtain a TIP designation, the proposed or existing credit union must submit a request to the Office of Consumer Financial Protection and Access Director. New charter applicants must follow the documentation requirements in Chapter 1. New charter applicants and existing credit unions must submit a business plan on how the credit union will serve the group with the request to serve the TIP. The business plan also must address how the credit union will verify the TIP. Examples of such verification include state licenses, professional licenses, organizational memberships, pay statements, union membership, or employer certification. The Office of Consumer Financial Protection and Access Director must approve this type of field of membership before a credit union can serve a TIP. Credit unions converting to a TIP can retain members of record but cannot add new members from its previous group or groups, unless the group or groups are part of the TIP.

Section II.B on Occupational Common Bond Amendments does not apply to a TIP common bond. Removing or changing a geographical limitation will be processed as a housekeeping amendment. If safety and soundness concerns are present, the Office of Consumer Financial Protection and Access Director may require additional information before the request can be processed.

Section II.H, on Other Persons Eligible for Credit Union Membership, applies to TIP based credit unions except for the corporate account provision which only applies to industry based TIPs. Credit unions with industry based TIPs may include corporations as members because they have the same commonality of interests as all employees in the industry. For example, an airline service TIP (industry) can serve an airline carrier (corporate account); however, a nurses TIP (profession) could not serve a hospital (corporate account) because not everyone working in the hospital shares the same profession.

If a TIP designated credit union wishes to convert to a different TIP or employer-based occupational common bond, or different charter type, it only retains members of record after the conversion. The Office of Consumer Financial Protection and Access Director, for safety and soundness reasons, may approve a TIP designated credit union to convert to its original field of membership.

II.B—Occupational Common Bond Amendments

II.B.1—General

Section 5 of every single occupational federal credit union's charter defines the field of membership the credit union can legally serve. Only those persons or legal entities specified in the field of membership can be served. There are a number of instances in which Section 5 must be amended by NCUA.

First, a group sharing the credit union's common bond is added to the field of membership. This may occur through various ways including agreement between the group and the credit union directly, or through a

merger, corporate acquisition, purchase and assumption (P&A), or spin-off.

Second, if the entire field of membership is acquired by another corporation, the credit union can serve the employees of the new corporation and any subsidiaries after receiving NCUA approval.

Third, a federal credit union qualifies to change its common bond from:

- A single occupational common bond to a single associational common bond;
-
- A single occupational common bond to a community charter; or
- A single occupational common bond to a multiple common bond.

Fourth, a federal credit union removes a portion of the group from its field of membership through agreement with the group, a spin-off, or because a portion of the group is no longer in existence.

An existing single occupational common bond federal credit union that submits a request to amend its charter must provide documentation to establish that the occupational common bond requirement has been met. The Office of Consumer Financial Protection and Access Director must approve all amendments to an occupational common bond credit union's field of membership.

II.B.Restructuring

If the single common bond group that comprises a federal credit union's field of membership undergoes a substantial restructuring, the result is often that portions of the group are sold or spun off. This requires a change to the credit union's field of membership. NCUA will not permit a single common bond credit union to maintain in its field of membership a sold or spun-off group to which it has been providing service unless the group otherwise qualifies for membership in the credit union or the credit union converts to a multiple common bond credit union.

If the group comprising the single common bond of the credit union merges with, or is acquired by, another group, the credit union can serve the new group resulting from the merger or acquisition after receiving a housekeeping amendment.

II.B.3—Economic Advisability

Prior to granting a common bond expansion, NCUA will examine the amendment's likely effect on the credit union's operations and financial condition. In most cases, the information needed for analyzing the effect of adding a particular group will be available to NCUA through the examination and financial and statistical reports; however, in particular cases, the Office of Consumer Financial Protection and Access Director may require additional information prior to making a decision.

II.B.Documentation Requirements

A federal credit union requesting a common bond expansion must submit an Application for Field of Membership Amendment (NCUA 4015–EZ) to the Office of Consumer Financial Protection and Access Director. An authorized credit union representative must sign the request.

II.C—NCUA's Procedures for Amending the Field of Membership

II.C.1—General

All requests for approval to amend a federal credit union's charter must be submitted to the Office of Consumer Financial Protection and Access Director.

II.C.2—Office of Consumer Financial Protection and Access Director Decision

NCUA staff will review all amendment requests in order to ensure compliance with NCUA policy.

Before acting on a proposed amendment, the Office of Consumer Financial Protection and Access Director may require an on-site review. In addition, the Office of Consumer Financial Protection and Access Director may, after taking into account the significance of the proposed field of membership amendment, require the applicant to submit a business plan addressing specific issues.

The financial and operational condition of the requesting credit union will be considered in every instance. NCUA will carefully consider the economic advisability of expanding the field of membership of a credit union with financial or operational problems.

In most cases, field of membership amendments will only be approved for credit unions that are operating satisfactorily. Generally, if a federal credit union is having difficulty providing service to its current membership, or is experiencing financial or other operational problems, it may have more difficulty serving an expanded field of membership.

Occasionally, however, an expanded field of membership may provide the basis for reversing current financial problems. In such cases, an amendment to expand the field of membership may be granted notwithstanding the credit union's financial or operational problems. The applicant credit union must clearly establish that the expanded field of membership is in the best interest of the members and will not increase the risk to the NCUSIF.

II.C.3—Office of Consumer Financial Protection and Access Director Approval

If the Office of Consumer Financial Protection and Access Director approves the requested amendment, the credit union will be issued an amendment to Section 5 of its charter.

II.C.4—Office of Consumer Financial Protection and Access Director Disapproval

When the Office of Consumer Financial Protection and Access Director disapproves any application, in whole or in part, to amend the field of membership under this chapter, the applicant will be informed in writing of the:

- Specific reasons for the action;
- Options to consider, if appropriate, for gaining approval; and
- Appeal procedure.

II.C.5—Appeal of Office of Consumer Financial Protection and Access Director Decision

If a field of membership expansion request, merger, or spin-off is denied by staff, the federal credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial. The appeal must be clearly identified as such and must address the specific reason(s) the federal credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access, or as applicable, the appropriate regional office or Office of National Examinations and Supervision Director. NCUA central office staff will make an independent review of the facts and present the appeal to the Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the office rendering the initial decision for reconsideration. A reconsideration will contain new and material evidence addressing the reasons for the initial denial. The office rendering the initial decision will have 30 days from the date of the receipt of the request for reconsideration to make a final decision. If the request is again denied, the applicant may proceed with the appeal process within 60 days of the date of the last denial. A second request for reconsideration will be treated as an appeal to the NCUA Board.

II.D—Mergers, Purchase and Assumptions, and Spin–Offs

In general, other than the addition of common bond groups, there are three additional ways a federal credit union with a single occupational common bond can expand its field of membership:

- By taking in the field of membership of another credit union through a common bond or emergency merger;
- By taking in the field of membership of another credit union through a common bond or emergency purchase and assumption (P&A); or
- By taking a portion of another credit union's field of membership through a common bond spin-off.

II.D.1—Mergers

Generally, the requirements applicable to field of membership expansions found in this chapter apply to mergers where the continuing credit union has a federal charter. That is, the two credit unions must share a common bond.

Where the merging credit union is state-chartered, the common bond rules applicable to a federal credit union apply.

Mergers must be approved by the NCUA regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union, and, as applicable, the state regulators.

If a single occupational credit union wants to merge into a multiple common bond or

community credit union, Section IV.D or Section V.D of this Chapter, respectively, should be reviewed.

II.D.Emergency Mergers

An emergency merger may be approved by NCUA without regard to common bond or other legal constraints. An emergency merger involves NCUA's direct intervention and approval. The credit union to be merged must either be insolvent or in danger of insolvency, as defined in the Glossary, and NCUA must determine that:

- An emergency requiring expeditious action exists;
- Other alternatives are not reasonably available; and
- The public interest would best be served by approving the merger.

If not corrected, conditions that could lead to insolvency include, but are not limited to:

- Abandonment by management;
- Loss of sponsor;
- Serious and persistent recordkeeping problems; or
-
- Serious and persistent operational concerns.

In an emergency merger situation, NCUA will take an active role in finding a suitable merger partner (continuing credit union). NCUA is primarily concerned that the continuing credit union has the financial strength and management expertise to absorb the troubled credit union without adversely affecting its own financial condition and stability.

As a stipulated condition to an emergency merger, the field of membership of the merging credit union may be transferred intact to the continuing federal credit union without regard to any common bond restrictions. Under this authority, therefore, a single occupational common bond federal credit union may take into its field of membership any dissimilar charter type.

The common bond characteristic of the continuing credit union in an emergency merger does not change. That is, even though the merging credit union is a multiple common bond or community, the continuing credit union will remain a single common bond credit union. Similarly, if the merging credit union is also an unlike single common bond, the continuing credit union will remain a single common bond credit union. Future common bond expansions will be based on the continuing credit union's original single common bond.

Emergency mergers involving federally insured credit unions in different NCUA field regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union and, as applicable, the state regulators.

II.D.Purchase and Assumption (P&A)

Another alternative for acquiring the field of membership of a failing credit union is through a consolidation known as a P&A. A P&A has limited application because, in most cases, the failing credit union must be placed into involuntary liquidation. In the few instances where a P&A may be appropriate, the assuming federal credit union, as with emergency mergers, may acquire the entire field of membership if the emergency merger criteria are satisfied. However, if the P&A does not meet the emergency merger criteria, it must be processed under the common bond requirements.

In a P&A processed under the emergency criteria, specified loans, shares, and certain other designated assets and liabilities, without regard to common bond restrictions, may also be acquired without changing the character of the continuing federal credit union for purposes of future field of membership amendments.

If the purchased and/or assumed credit union's field of membership does not share a common bond with the purchasing and/or assuming credit union, then the continuing credit union's original common bond will be controlling for future common bond expansions.

P&As involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the purchased and/or assumed credit union and, as applicable, the state regulators.

II.D.4—Spin-Offs

A spin-off occurs when, by agreement of the parties, a portion of the field of membership, assets, liabilities, shares, and capital of a credit union are transferred to a new or existing credit union. A spin-off is unique in that usually one credit union has a field of membership expansion and the other loses a portion of its field of membership.

All common bond requirements apply regardless of whether the spun-off group becomes a new credit union or goes to an existing federal charter.

The request for approval of a spin-off must be supported with a plan that addresses, at a minimum:

- Why the spin-off is being requested;
- What part of the field of membership is to be spun off;
- Whether the affected credit unions have a common bond (applies only to single occupational credit unions);
- Which assets, liabilities, shares, and capital are to be transferred;
- The financial impact the spin-off will have on the affected credit unions;
- The ability of the acquiring credit union to effectively serve the new members;
- The proposed spin-off date; and
- Disclosure to the members of the requirements set forth above.

The spin-off request must also include current financial statements from the affected credit unions and the proposed voting ballot.

For federal credit unions spinning off a group, membership notice and voting requirements and procedures are the same as for mergers (see part 708 of the NCUA Rules and Regulations), except that only the members directly affected by the spin-off—those whose shares are to be transferred—are permitted to vote. Members whose shares are not being transferred will not be afforded the opportunity to vote. All members of the group to be spun off (whether they voted in favor, against, or not at all) will be transferred if the spin-off is approved by the voting membership. Voting requirements for federally insured state credit unions are governed by state law.

Spin-offs involving federally insured credit unions in different NCUA regions must be approved by all regional directors and, if applicable, Office of National Examinations and Supervision Director where the credit unions are headquartered and the state regulators, as applicable. Spin-offs in the same region also require approval by the state regulator, as applicable. Spin-offs involving the creation of a new federally insured credit union require the approval of the Office of Consumer Financial Protection and Access Director. The Office of Consumer Financial Protection and Access also provides advice regarding field of membership compatibility when appropriate.

II.E—Overlaps

II.E.1—General

An overlap exists when a group of persons is eligible for membership in two or more credit unions. NCUA will permit single occupational federal credit unions to overlap any other charter without performing an overlap analysis.

II.E.Organizational Restructuring

A federal credit union's field of membership will always be governed by the common bond descriptions contained in Section 5 of its charter. Where a sponsor organization expands its operations internally, by acquisition or otherwise, the credit union may serve these new entrants to its field of membership if they are part of the common bond described in Section 5. NCUA will permit a complete overlap of the credit unions' fields of membership.

If a sponsor organization sells off a group, new members can no longer be served unless they otherwise qualify for membership in the credit union or it converts to a multiple common bond charter.

Credit unions must submit documentation explaining the restructuring and providing information regarding the new organizational structure.

II.E.3—Exclusionary Clauses

An exclusionary clause is a limitation precluding the credit union from serving the primary members of a portion of a group otherwise included in its field of membership. NCUA no longer grants exclusionary clauses. Those granted prior to the adoption of this new Chartering and Field of Membership Manual will remain in effect unless the credit unions agree to remove them or one of the affected credit unions submits a housekeeping amendment to have it removed.

II.F—Charter Conversion

A single occupational common bond federal credit union may apply to convert to a community charter provided the field of

membership requirements of the community charter are met. Groups within the existing charter which cannot qualify in the new charter cannot be served except for members of record, or groups or communities obtained in an emergency merger or P&A. A credit union must notify all groups that will be removed from the field of membership as a result of conversion. Members of record can continue to be served. Also, in order to support a case for a conversion, the applicant federal credit union may be required to develop a detailed business plan as specified in Chapter 2, Section V.A.3.

A single occupational common bond federal credit union may apply to convert to a multiple common bond charter by adding a non-common bond group that is within a reasonable proximity of a service facility. Groups within the existing charter may be retained and continue to be served. However, future amendments, including any expansions of the original single common bond group, must be done in accordance with multiple common bond policy.

II.G—Removal of Groups From the Field of Membership

A credit union may request removal of a portion of the common bond group from its field of membership for various reasons. The most common reasons for this type of amendment are:

- The group is within the field of membership of two credit unions and one wishes to discontinue service;
- The federal credit union cannot continue to provide adequate service to the group;
- The group has ceased to exist;
- The group does not respond to repeated requests to contact the credit union or refuses to provide needed support; or
- The group initiates action to be removed from the field of membership.

When a federal credit union requests an amendment to remove a group from its field of membership, the Office of Consumer Financial Protection and Access Director will determine why the credit union desires to remove the group. If the Office of Consumer Financial Protection and Access Director concurs with the request, membership will continue for those who are already members under the ''once a member, always a member'' provision of the Federal Credit Union Act.

II.H—Other Persons Eligible for Credit Union Membership

A number of persons, by virtue of their close relationship to a common bond group, may be included, at the charter applicant's option, in the field of membership. These include the following:

- Spouses of persons who died while within the field of membership of this credit union;
- Employees of this credit union;
- Persons retired as pensioners or annuitants from the above employment;
- Volunteers;
- Members of the immediate family or household;
-
- Honorably discharged veterans who served in any of the Armed Services of the United States listed in this charter;

Organizations of such persons; and

- Corporate or other legal entities in this charter.

Immediate family is defined as spouse, child, sibling, parent, grandparent, or grandchild. This includes stepparents, stepchildren, stepsiblings, and adoptive relationships.

Household is defined as persons living in the same residence maintaining a single economic unit.

Membership eligibility is extended only to individuals who are members of an ''immediate family or household'' of a credit union member. It is not necessary for the primary member to join the credit union in order for the immediate family or household member of the primary member to join, provided the immediate family or household clause is included in the field of membership. However, it is necessary for the immediate family member or household member to first join in order for that person's immediate family member or household member to join the credit union. A credit union can adopt a more restrictive definition of immediate family or household.

Volunteers, by virtue of their close relationship with a sponsor group, may be included. Examples include volunteers working at a hospital or school.

Under the Federal Credit Union Act, once a person becomes a member of the credit union, such person may remain a member of the credit union until the person chooses to withdraw or is expelled from the membership of the credit union. This is commonly referred to as ''once a member, always a member.'' The ''once a member, always a member'' provision does not prevent a credit union from restricting services to members who are no longer within the field of membership.

III—Associational Common Bond

III.A.1—General

A single associational federal credit union may include in its field of membership, regardless of location, all members and employees of a recognized association. A single associational common bond consists of individuals (natural persons) and/or groups (non-natural persons) whose members participate in activities developing common loyalties, mutual benefits, and mutual interests. Separately chartered associational groups can establish a single common bond relationship if they are integrally related and share common goals and purposes. For example, two or more churches of the same denomination, Knights of Columbus Councils, or locals of the same union can qualify as a single associational common bond. Individuals and groups eligible for membership in a single associational credit union can include the following:

- Natural person members of the association (for example, members of a union or church members);
- Non-natural person members of the association;
- Employees of the association (for example, employees of the labor union or employees of the church); and
- The association.

Generally, a single associational common bond does not include a geographic definition and can operate nationally. However, a proposed or existing federal credit union may limit its field of membership to a single association or geographic area. NCUA may impose a geographic limitation if it is determined that the applicant credit union does not have the ability to serve a larger group or there are other operational concerns. All single associational common bonds should include a definition of the group that may be served based on the association's charter, bylaws, and any other equivalent documentation.

Applicants for a single associational common bond federal credit union charter or a field of membership amendment to include an association must provide, at the request of NCUA, a copy of the association's charter, bylaws, or other equivalent documentation, including any legal documents required by the state or other governing authority. The associational sponsor itself may also be included in the field of membership—*e.g.,* ''Sprocket Association''—and will be shown in the last clause of the field of membership.

III.A.1.a—Threshold Requirement Regarding the Purpose for Which an Associational Group Is Formed and the Totality of the Circumstances Criteria

As a threshold matter, when reviewing an application to include an association in a federal credit union's field of membership, NCUA will determine if the association has been formed primarily for the purpose of expanding credit union membership. If NCUA makes such a determination, then the analysis ends and the association is denied inclusion in the federal credit union's field of membership. If NCUA determines that the association was formed to serve some other separate function as an organization, then NCUA will apply the following totality of the circumstances test to determine if the association satisfies the associational common bond requirements. The totality of the circumstances test consists of the following factors:

1. Whether the association provides opportunities for members to participate in the furtherance of the goals of the association;
2. Whether the association maintains a membership list;
1.
3. Whether the association sponsors other activities;
4. Whether the association's membership eligibility requirements are authoritative;
5. Whether members pay dues;
6. Whether the members have voting rights; to meet this requirement, members need not vote directly for an officer, but may vote for a delegate who in turn represents the members' interests;
7. The frequency of meetings; and
8. Separateness—NCUA reviews if there is corporate separateness between the group and the federal credit union. The group and the federal credit union must operate in a way that demonstrates the separate corporate existence of each entity. Specifically, this means the federal credit union's and the group's respective business transactions, accounts, and corporate records are not intermingled.

No one factor alone is determinative of membership eligibility as an association. The totality of the circumstances controls over any individual factor in the test. However, NCUA's primary focus will be on factors 1–4.

III.A.1.Pre-Approved Groups

NCUA automatically approves the below groups as satisfying the associational common bond provisions. NCUA only approves regular members of an approved group. Honorary, affiliate, or non-regular members do not qualify.

These groups are:

(1) Alumni associations;

(2) Religious organizations, including churches or groups of related churches;

(3) Electric cooperatives;

(4) Homeowner associations;

(1)

(5) Labor unions;

(6) Scouting groups;

(7) Parent teacher associations (PTAs) organized at the local level to serve a single school district;

(8) Chamber of commerce groups (members only and not employees of members);

(9) Athletic booster clubs whose members have voting rights;

(10) Fraternal organizations or civic groups with a mission of community service whose members have voting rights;

(11) Organizations having a mission based on preserving or furthering the culture of a particular national or ethnic origin; and

(12) Organizations promoting social interaction or educational initiatives among persons sharing a common occupational profession.

III.A.1.c—Additional Information

A support group whose members are continually changing or whose duration is temporary may not meet the single associational common bond criteria. Each class of member will be evaluated based on the totality of the circumstances. Individuals or honorary members who only make donations to the association are not eligible to join the credit union.

Student groups (*e.g.,* students enrolled at a public, private, or parochial school) may constitute either an associational or occupational common bond. For example, students enrolled at a church sponsored school could share a single associational common bond with the members of that church and may qualify for a federal credit union charter. Similarly, students enrolled at a university, as a group by itself, or in conjunction with the faculty and employees of the school, could share a single occupational common bond and may qualify for a federal credit union charter.

Tenant groups, consumer groups, and other groups of persons having an ''interest in'' a particular cause and certain consumer cooperatives may also qualify as an association.

Associations based primarily on a client-customer relationship do not meet associational common bond requirements. Health clubs are an example of a group not meeting associational common bond requirements, including YMCAs. However, having an incidental client-customer relationship does not preclude an associational charter as long as the associational common bond requirements are met. For example, a fraternal association that offers insurance, which is not a condition of membership, may qualify as a valid associational common bond.

III.A.2—Subsequent Changes to Association's Bylaws

If the association's membership or geographical definitions in its charter and bylaws are changed subsequent to the effective date stated in the field of membership, the credit union must submit the revised charter or bylaws for NCUA's consideration and approval prior to serving members of the association added as a result of the change.

III.A.3—Sample Single Associational Common Bonds

Some examples of associational common bonds are:

- Regular members of Locals 10 and 13, IBEW, in Florida, who qualify for membership in accordance with their charter and bylaws in effect on May 20, 2001;
- Members of the Hoosier Farm Bureau in Grant, Logan, or Lee Counties of Indiana, who qualify for membership in accordance with its charter and bylaws in effect on March 7, 1997;
- Members of the Shalom Congregation in Chevy Chase, Maryland;
-
- Regular members of the Corporate Executives Association, located in Westchester, New York, who qualify for membership in accordance with its charter and bylaws in effect on December 1, 1997;
- Members of the University of Wisconsin Alumni Association, located in Green Bay, Wisconsin;
- Members of the Marine Corps Reserve Officers Association; or
- Members of St. John's Methodist Church and St. Luke's Methodist Church, located in Toledo, Ohio.

Some examples of insufficiently defined single associational common bonds are:

- All Lutherans in the United States (too broadly defined); or
- Veterans of U.S. military service (group is too broadly defined; no formal association of all members of the group).

Some examples of unacceptable single associational common bonds are:

- Alumni of Amos University (no formal association);
- Customers of Fleetwood Insurance Company (policyholders or primarily customer/client relationships do not meet associational standards);
- Employees of members of the Reston, Virginia, Chamber of Commerce (not a sufficiently close tie to the associational common bond); or
- Members of St. John's Lutheran Church and St. Mary's Catholic Church located in Anniston, Alabama (churches are not of the same denomination).

III.B—Associational Common Bond Amendments

III.B.1—General

Section 5 of every associational federal credit union's charter defines the field of membership the credit union can legally serve. Only those persons who, or legal entities that, join the credit union and are specified in the field of membership can be served. There are three instances in which Section 5 must be amended by NCUA.

First, a group that shares the credit union's common bond is added to the field of membership. This may occur through various ways including agreement between the group and the credit union directly, or through a merger, purchase and assumption (P&A), or spin-off.

Second, a federal credit union qualifies to change its common bond from:

- A single associational common bond to a single occupational common bond;
- A single associational common bond to a community charter; or
- A single associational common bond to a multiple common bond.

Third, a federal credit union removes a portion of the group from its field of membership through agreement with the group, a spin-off, or a portion of the group that is no longer in existence.

An existing single associational federal credit union that submits a request to amend its charter must provide documentation to establish that the associational common bond requirement has been met. The Office of Consumer Financial Protection and Access Director must approve all amendments to an associational common bond credit union's field of membership.

III.B.Organizational Restructuring

If the single common bond group that comprises a federal credit union's field of membership undergoes a substantial restructuring, the result is often that portions of the group are sold or spun off. This is an event requiring a change to the credit union's field of membership. NCUA may not permit a single associational credit union to maintain in its field of membership a sold or spun-off group to which it has been providing service unless the group otherwise qualifies for membership in the credit union or the credit union converts to a multiple common bond credit union.

If the group comprising the single common bond of the credit union merges with, or is acquired by, another group, the credit union can serve the new group resulting from the merger or acquisition after receiving a housekeeping amendment.

III.B.3—Economic Advisability

Prior to granting a common bond expansion, NCUA will examine the amendment's likely impact on the credit union's operations and financial condition. In most cases, the information needed for analyzing the effect of adding a particular group will be available to NCUA through the examination and financial and statistical reports; however, in particular cases, the Office of Consumer Financial Protection and Access Director may require additional information prior to making a decision.

III.B.Documentation Requirements

A federal credit union requesting a common bond expansion must submit an Application for Field of Membership Amendment (NCUA 4015–EZ) to the Office of Consumer Financial Protection and Access Director. An authorized credit union representative must sign the request.

III.C—NCUA Procedures for Amending the Field of Membership

III.C.1—General

All requests for approval to amend a federal credit union's charter must be submitted to the Office of Consumer Financial Protection and Access Director.

III.C.C.2—Office of Consumer Financial Protection and Access Director Decision

NCUA staff will review all amendment requests in order to ensure conformance to NCUA policy.

Before acting on a proposed amendment, the Office of Consumer Financial Protection and Access Director may require an on-site review. In addition, the Office of Consumer Financial Protection and Access Director may, after taking into account the significance of the proposed field of membership amendment, require the applicant to submit a business plan addressing specific issues.

The financial and operational condition of the requesting credit union will be considered in every instance. The economic advisability of expanding the field of membership of a credit union with financial or operational problems must be carefully considered.

In most cases, field of membership amendments will only be approved for credit unions that are operating satisfactorily. Generally, if a federal credit union is having difficulty providing service to its current membership, or is experiencing financial or other operational problems, it may have more difficulty serving an expanded field of membership.

Occasionally, however, an expanded field of membership may provide the basis for reversing current financial problems. In such cases, an amendment to expand the field of membership may be granted notwithstanding the credit union's financial or operational problems. The applicant credit union must clearly establish that the expanded field of membership is in the best interest of the members and will not increase the risk to the NCUSIF.

III.C.3—Office of Consumer Financial Protection and Access Director Approval

If the Office of Consumer Financial Protection and Access Director approves the requested amendment, the credit union will be issued an amendment to Section 5 of its charter.

III.C.4—Office of Consumer Financial Protection and Access Director Disapproval

When the Office of Consumer Financial Protection and Access Director disapproves any application, in whole or in part, to amend the field of membership under this chapter, the applicant will be informed in writing of the:

- Specific reasons for the action;
- Options to consider, if appropriate, for gaining approval; and
- Appeal procedures.

III.C.5—Appeal of Office of Consumer Financial Protection and Access Director Decision

If a field of membership expansion request, merger, or spin-off is denied by staff, the federal credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial and must be clearly identified as such and address the reason(s) the federal credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access, or as applicable, the appropriate regional office or Office of National Examinations and Supervision Director. NCUA central office staff will make an independent review of the facts and present the appeal to the NCUA Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the office rendering the initial decision for reconsideration. A reconsideration will contain new and material evidence addressing the reasons for the initial denial. The office rendering the initial decision will have 30 days from the date of the receipt of the request for reconsideration to make a final decision. If the request is again denied, the applicant may proceed with the appeal process within 60 days of the date of the last denial. A second request for reconsideration will be treated as an appeal to the NCUA Board.

III.D—Mergers, Purchase and Assumptions, and Spin-Offs

In general, other than the addition of common bond groups, there are three additional ways a federal credit union with a single associational common bond can expand its field of membership:

- By taking in the field of membership of another credit union through a common bond or emergency merger;
- By taking in the field of membership of another credit union through a common bond or emergency purchase and assumption (P&A); or
- By taking a portion of another credit union's field of membership through a common bond spin-off.

III.D.1—Mergers

Generally, the requirements applicable to field of membership expansions found in this section apply to mergers where the continuing credit union is a federal charter. That is, the two credit unions must share a common bond.

Where the merging credit union is state-chartered, the common bond rules applicable to a federal credit union apply.

Mergers must be approved by the NCUA regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union, and, as applicable, the state regulators.

If a single associational credit union wants to merge into a multiple common bond or community credit union, Section IV.D or Section V.D of this Chapter, respectively, should be reviewed.

III.D.Emergency Mergers

An emergency merger may be approved by NCUA without regard to common bond or other legal constraints. An emergency merger involves NCUA's direct intervention and approval. The credit union to be merged must either be insolvent or in danger of insolvency, as defined in the Glossary, and NCUA must determine that:

- An emergency requiring expeditious action exists;
- Other alternatives are not reasonably available; and
- The public interest would best be served by approving the merger.

If not corrected, conditions that could lead to insolvency include, but are not limited to:

- Abandonment by management;
- Loss of sponsor;
- Serious and persistent record-keeping problems; or
- Serious and persistent operational concerns.

In an emergency merger situation, NCUA will take an active role in finding a suitable merger partner (continuing credit union). NCUA is primarily concerned that the continuing credit union has the financial strength and management expertise to absorb the troubled credit union without adversely affecting its own financial condition and stability.

As a stipulated condition to an emergency merger, the field of membership of the merging credit union may be transferred intact to the continuing federal credit union without regard to any common bond restrictions. Under this authority, therefore, a single associational common bond federal credit union may take into its field of membership any dissimilar charter type.

The common bond characteristic of the continuing credit union in an emergency merger does not change. That is, even though the merging credit union is a multiple common bond or community, the continuing credit union will remain a single common bond credit union. Similarly, if the merging credit union is an unlike single common bond, the continuing credit union will remain a single common bond credit union. Future common bond expansions will be based on the continuing credit union's single common bond.

Emergency mergers involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union and, as applicable, the state regulators.

III.D.Purchase and Assumption (P&A)

Another alternative for acquiring the field of membership of a failing credit union is

through a consolidation known as a P&A. A P&A has limited application because, in most cases, the failing credit union must be placed into involuntary liquidation. In the few instances where a P&A may be appropriate, the assuming federal credit union, as with emergency mergers, may acquire the entire field of membership if the emergency merger criteria are satisfied. However, if the P&A does not meet the emergency merger criteria, it must be processed under the common bond requirements.

In a P&A processed under the emergency criteria, specified loans, shares, and certain other designated assets and liabilities, without regard to common bond restrictions, may also be acquired without changing the character of the continuing federal credit union for purposes of future field of membership amendments.

If the purchased and/or assumed credit union's field of membership does not share a common bond with the purchasing and/or assuming credit union, then the continuing credit union's original common bond will be controlling for future common bond expansions.

P&As involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the purchased and/or assumed credit union and, as applicable, the state regulators.

III.D.4—Spin-Offs

A spin-off occurs when, by agreement of the parties, a portion of the field of membership, assets, liabilities, shares, and capital of a credit union are transferred to a new or existing credit union. A spin-off is unique in that usually one credit union has a field of membership expansion and the other loses a portion of its field of membership.

All common bond requirements apply regardless of whether the spun-off group becomes a new credit union or goes to an existing federal charter.

The request for approval of a spin-off must be supported with a plan that addresses, at a minimum:

- Why the spin-off is being requested;
- What part of the field of membership is to be spun off;
- Whether the affected credit unions have the same common bond (applies only to single associational credit unions);
- Which assets, liabilities, shares, and capital are to be transferred;
- The financial impact the spin-off will have on the affected credit unions;
- The ability of the acquiring credit union to effectively serve the new members;
- The proposed spin-off date; and
- Disclosure to the members of the requirements set forth above.

The spin-off request must also include current financial statements from the affected credit unions and the proposed voting ballot.

For federal credit unions spinning off a group, membership notice and voting requirements and procedures are the same as for mergers (see part 708 of the NCUA Rules and Regulations), except that only the members directly affected by the spin-off—those whose shares are to be transferred—are permitted to vote. Members whose shares are not being transferred will not be afforded the opportunity to vote. All members of the group to be spun off (whether they voted in favor, against, or not at all) will be transferred if the spin-off is approved by the voting membership. Voting requirements for federally insured state credit unions are governed by state law.

Spin-offs involving federally insured credit unions in different NCUA regions must be approved by all regional directors and, if applicable, Office of National Examinations and Supervision Director where the credit unions are headquartered and the state regulators, as applicable. Spin-offs in the same region also require approval by the state regulator, as applicable. Spin-offs involving the creation of a new federally insured credit union require the approval of the Office of Consumer Financial Protection and Access Director. The Office of Consumer Financial Protection and Access also provides advice regarding field of membership compatibility when appropriate.

III.E—Overlaps

III.E.1—General

An overlap exists when a group of persons is eligible for membership in two or more credit unions. NCUA will permit single associational federal credit unions to overlap any other charters without performing an overlap analysis.

III.E.Organizational Restructuring

A federal credit union's field of membership will always be governed by the common bond descriptions contained in Section 5 of its charter. Where a sponsor organization expands its operations internally, by acquisition or otherwise, the credit union may serve these new entrants to its field of membership if they are part of the common bond described in Section 5. NCUA will permit a complete overlap of the credit unions' fields of membership. If a sponsor organization sells off a group, new members can no longer be served unless they otherwise qualify for membership in the credit union or it converts to a multiple common bond.

Credit unions must submit documentation explaining the restructuring and providing information regarding the new organizational structure.

III.E.3—Exclusionary Clauses

An exclusionary clause is a limitation precluding the credit union from serving the primary members of a portion of a group otherwise included in its field of membership. NCUA no longer grants exclusionary clauses. Those granted prior to the adoption of this new Chartering and Field of Membership Manual will remain in effect unless the credit unions agree to remove them or one of the affected credit unions submits a housekeeping amendment to have it removed.

III.F—Charter Conversions

A single associational common bond federal credit union may apply to convert to a community charter provided the field of membership requirements of the community charter are met. Groups within the existing charter which cannot qualify in the new charter cannot be served except for members of record, or groups or communities obtained in an emergency merger or P&A. A credit union must notify all groups that will be removed from the field of membership as a result of conversion. Members of record can continue to be served. Also, in order to support a case for a conversion, the applicant federal credit union may be required to develop a detailed business plan as specified in Chapter 2, Section V.A.3.

A single associational common bond federal credit union may apply to convert to a multiple common bond charter by adding a non-common bond group that is within a reasonable proximity of a service facility. Groups within the existing charter may be retained and continue to be served. However, future amendments, including any expansions of the original single common bond group, must be done in accordance with multiple common bond policy.

III.G—Removal of Groups From the Field of Membership

A credit union may request removal of a portion of the common bond group from its field of membership for various reasons. The most common reasons for this type of amendment are:

- The group is within the field of membership of two credit unions and one wishes to discontinue service;
- The federal credit union cannot continue to provide adequate service to the group;
- The group has ceased to exist;
- The group does not respond to repeated requests to contact the credit union or refuses to provide needed support; or
- The group initiates action to be removed from the field of membership.

When a federal credit union requests an amendment to remove a group from its field of membership, the Office of Consumer Financial Protection and Access Director will determine why the credit union desires to remove the group. If the Office of Consumer Financial Protection and Access Director concurs with the request, membership will continue for those who are already members under the ''once a member, always a member'' provision of the Federal Credit Union Act.

III.H—Other Persons Eligible for Credit Union Membership

A number of persons by virtue of their close relationship to a common bond group may be included, at the charter applicant's option, in the field of membership. These include the following:

- Spouses of persons who died while within the field of membership of this credit union;
- Employees of this credit union;
- Volunteers;
- Members of the immediate family or household;
-

• Honorably discharged veterans who served in any of the Armed Services of the United States in this charter;

Organizations of such persons; and

• Corporate or other legal entities in this charter.

Immediate family is defined as spouse, child, sibling, parent, grandparent, or grandchild. This includes stepparents, stepchildren, stepsiblings, and adoptive relationships.

Household is defined as persons living in the same residence maintaining a single economic unit.

Membership eligibility is extended only to individuals who are members of an ''immediate family or household'' of a credit union member. It is not necessary for the primary member to join the credit union in order for the immediate family or household member of the primary member to join, provided the immediate family or household clause is included in the field of membership. However, it is necessary for the immediate family member or household member to first join in order for that person's immediate family member or household member to join the credit union. A credit union can adopt a more restrictive definition of immediate family or household.

Volunteers, by virtue of their close relationship with a sponsor group, may be included. One example is volunteers working at a church.

Under the Federal Credit Union Act, once a person becomes a member of the credit union, such person may remain a member of the credit union until the person chooses to withdraw or is expelled from the membership of the credit union. This is commonly referred to as ''once a member, always a member.'' The ''once a member, always a member'' provision does not prevent a credit union from restricting services to members who are no longer within the field of membership.

IV—Multiple Occupational/Associational Common Bonds

IV.A.1—General

A federal credit union may be chartered to serve a combination of distinct, definable single occupational and/or associational common bonds. This type of credit union is called a multiple common bond credit union. Each group in the field of membership must have its own occupational or associational common bond. For example, a multiple common bond credit union may include two unrelated employers, or two unrelated associations, or a combination of two or more employers or associations. Additionally, these groups must be within reasonable geographic proximity of the credit union. That is, the groups must be within the service area of one of the credit union's service facilities. These groups are referred to as select groups. A multiple common bond credit union cannot include a TIP or expand using single common bond criteria.

Employment in a corporation or other legal entity which is related to another legal entity (such as a company under contract to, and possessing a strong dependency relationship with, the other company) makes that person part of the occupational common bond of a select employee group within a multiple common bond. In this context, a ''strong dependency relationship'' is a relationship in which the entities rely on each other as measured by a pattern of regularly doing business with each other, for example, as documented by the number, the term length, and the dollar volume of prior and pending contracts between them.

A multiple common bond credit union's charter may also combine individual occupational groups that each consist of employees of a retailer or other business tenant of an industrial park, a shopping mall, office park or office building (each ''a park''). To be able to have this type of clause in its charter, the multiple common bond credit union first must receive a request from an authorized representative of the group or the park to establish credit union service. The park must be within the multiple common bond credit union's service area, and each occupational group must have fewer than 3,000 employees, who are eligible for membership only for so long as each is employed by a park tenant. Under this clause, a multiple common bond credit union can enroll group employees only while the group's retail or business employer is a park tenant, but such credit unions are free to serve employees of new groups under the above conditions as each respective employer becomes a park tenant.

A federal credit union's service area is the area that can reasonably be served by the service facilities accessible to the groups within the field of membership. The service area will most often coincide with that geographic area primarily served by the service facility. Additionally, the groups served by the credit union must have access to the service facility. The non-availability of other credit union service is a factor to be considered in determining whether the group is within reasonable proximity of a credit union wishing to add the group to its field of membership.

A service facility for multiple common bond credit unions is defined as a place where shares are accepted for members' accounts, loan applications are accepted or loans are disbursed. This definition includes a credit union owned branch, a mobile branch, an office operated on a regularly scheduled weekly basis, a credit union owned ATM, or a credit union owned electronic facility that meets, at a minimum, these requirements. A service facility also includes a shared branch or a shared branch network if either: (1) The credit union has an ownership interest in the service facility either directly or through a CUSO or similar organization; or (2) the service facility is local to the credit union and the credit union is an authorized participant in the service center. This definition does not include the credit union's Internet Web site.

The select group as a whole will be considered to be within a credit union's service area when:

• A majority of the persons in a select group live, work, or gather regularly within the service area;

• The group's headquarters is located within the service area; or

• The group's ''paid from'' or ''supervised from'' location is within the service area.

IV.A.2—Sample Multiple Common Bond Field of Membership

An example of a multiple common bond field of membership is:

''The field of membership of this federal credit union shall be limited to the following:

1. Employees of Teltex Corporation who work in Wilmington, Delaware;

2. Partners and employees of Smith & Jones, Attorneys at Law, who work in Wilmington, Delaware;

3. Members of the M&L Association in Wilmington, Delaware, who qualify for membership in accordance with its charter and bylaws in effect on December 31, 1997;

4. Employees of tenants of MJB Office Park under the following conditions:

—Each tenant's employees form an individual occupational group;

—the tenant has fewer than 3,000 employees working at MJB Office Park; and

—those employees work in MJB Office Park's Wilmington, Delaware location,''

IV.B—Multiple Common Bond Amendments

IV.B.1—General

Section 5 of every multiple common bond federal credit union's charter defines the field of membership and select groups the credit union can legally serve. Only those persons or legal entities specified in the field of membership can be served. There are a number of instances in which Section 5 must be amended by NCUA.

First, a new select group is added to the field of membership. This may occur through agreement between the group and the credit union directly, or through a merger, corporate acquisition, purchase and assumption (P&A), or spin-off.

Second, a federal credit union qualifies to change its charter from:

• A single occupational or associational charter to a multiple common bond charter;

• A multiple common bond to a single occupational or associational charter;

• A multiple common bond to a community charter; or

• A community to a multiple common bond charter.

Third, a federal credit union removes a group from its field of membership through agreement with the group, a spin-off, or because the group no longer exists.

IV.B.2—Numerical Limitation of Select Groups

An existing multiple common bond federal credit union that submits a request to amend its charter must provide documentation to establish that the multiple common bond requirements have been met. The Office of Consumer Financial Protection and Access Director must approve all amendments to a multiple common bond credit union's field of membership.

NCUA will approve groups to a credit union's field of membership if the agency determines in writing that the following criteria are met:

• The credit union has not engaged in any unsafe or unsound practice, as determined by the Office of Consumer Financial Protection and Access Director, with input from the appropriate regional director or Office of

National Examinations and Supervision Director, which is material during the one year period preceding the filing to add the group;

• The credit union is ''adequately capitalized'' pursuant to Part 702 of NCUA's Rules and Regulations. For low-income credit unions or credit unions chartered less than ten years, the Office of Consumer Financial Protection and Access Director, with input from the appropriate regional director or Office of National Examinations and Supervision Director, may determine that a less than ''adequately capitalized'' credit union can qualify for an expansion if it is making reasonable progress toward becoming ''adequately capitalized.'' For any other credit union, the Office of Consumer Financial Protection and Access Director, with input from the appropriate regional director or Office of National Examinations and Supervision Director, may determine that a less than ''adequately capitalized'' credit union can qualify for an expansion if it is making reasonable progress toward becoming ''adequately capitalized,'' and the addition of the group would not adversely affect the credit union's capitalization level;

• The credit union has the administrative capability to serve the proposed group and the financial resources to meet the need for additional staff and assets to serve the new group;

• Any potential harm the expansion may have on any other credit union and its members is clearly outweighed by the probable beneficial effect of the expansion. With respect to a proposed expansion's effect on other credit unions, the requirements on overlapping fields of membership set forth in Section IV.E of this Chapter are also applicable; and

• If the formation of a separate credit union by such group is not practical and consistent with reasonable standards for the safe and sound operation of a credit union.

The Federal Credit Union Act presumes that a group of 3,000 or more primary potential members is able to form its own stand-alone credit union unless NCUA determines that it is infeasible to do so for reasons such as:

(i) The group lacks sufficient volunteer and other resources to support the efficient and effective operation of its own credit union;

(ii) the group does not meet criteria that the Board has determined to be an important indicator of success in establishing and managing a new credit union, including demographic characteristics such as the geographic location of members, the diversity of ages and income levels among members, and other factors that may affect such a credit union's financial viability and stability; or

(iii) the group would be unlikely to operate a safe and sound credit union.

As such, NCUA requires additional information when a multiple common bond credit union applies to add a group of 3,000 or more primary potential members. For groups between 3,000 and 4,999 potential members, NCUA requires documentation indicating the group has a lack of available subsidies, interest among the group's members, and sufficient resources. For such cases NCUA, in its discretion, will accept a written statement indicating these conditions exist as sufficient documentation the group cannot form its own credit union. Groups with 5,000 or more members will be subject to the standard document requirements as discussed later in this chapter, requiring a group to fully describe its inability to establish a new single common bond credit union.

IV.B.Documentation Requirements

A multiple common bond credit union requesting a select group expansion must submit a formal written request, using the Application for Field of Membership Amendment (NCUA 4015–EZ, NCUA 4015–A or NCUA 4015) to the Office of Consumer Financial Protection and Access Director. An authorized credit union representative must sign the request.

The NCUA 4015–EZ (for groups less than 3,000 potential members) must be accompanied by the following:

• A letter, or equivalent documentation, from the group requesting credit union service. This letter must indicate:

• That the group wants to be added to the applicant federal credit union's field of membership;

• The number of persons currently included within the group to be added and their locations; and

• The group's proximity to the credit union's nearest service facility.

• The most recent copy of the group's charter and bylaws or equivalent documentation (for associational groups).

The NCUA 4015–A (for groups between 3,000 and 4,999 primary potential members) must be accompanied by the following:

• A letter, or equivalent documentation, from the group requesting credit union service. This letter must indicate:

• That the group wants to be added to the federal credit union's field of membership;

• The number of persons currently included within the group to be added and their locations;

• The group's proximity to credit union's nearest service facility, and

• Why the formation of a separate credit union for the group is not practical or consistent with safety and soundness standards because of a lack of available subsidies, interest among the group's members, and sufficient resources.

The NCUA 4015 (for groups of 5,000 or more primary potential members) must be accompanied by the following:

• A letter, or equivalent documentation, from the group requesting credit union service. This letter must indicate:

• That the group wants to be added to the federal credit union's field of membership;

• Whether the group presently has other credit union service available;

• The number of persons currently included within the group to be added and their locations;

• The group's proximity to credit union's nearest service facility, and

• Why the formation of a separate credit union for the group is not practical or consistent with safety and soundness standards. A credit union need not address every item on the list, simply those issues that are relevant to its particular request:

Member location—whether the membership is widely dispersed or concentrated in a central location.

Demographics—the employee turnover rate, economic status of the group's members, and whether the group is more apt to consist of savers and/or borrowers.

Market competition—the availability of other financial services.

Desired services and products—the type of services the group desires in comparison to the type of services a new credit union could offer.

Sponsor subsidies—the availability of operating subsidies.

The desire of the sponsor—the extent of the sponsor's interest in supporting a credit union charter.

Employee interest—the extent of the employees' interest in obtaining a credit union charter.

Evidence of past failure—whether the group previously had its own credit union or previously filed for a credit union charter.

Administrative capacity to provide services—will the group have the management expertise to provide the services requested.

• If the group is eligible for membership in any other credit union, documentation must be provided to support inclusion of the group under the overlap standards set forth in Section IV.E of this Chapter; and

• The most recent copy of the group's charter and bylaws or equivalent documentation (for associational groups).

IV.B.Restructuring

If a select group within a federal credit union's field of membership undergoes a substantial restructuring, a change to the credit union's field of membership may be required if the credit union is to continue to provide service to the select group. NCUA permits a multiple common bond credit union to maintain in its field of membership a sold, spun-off, or merged select group to which it has been providing service. This type of amendment to the credit union's charter is not considered an expansion; therefore, the criteria relating to adding new groups are not applicable.

When two groups merge and each is in the field of membership of a credit union, then both (or all affected) credit unions can serve the resulting merged group, subject to any existing geographic limitation and without regard to any overlap provisions. However, the credit unions cannot serve the other multiple groups that may be in the field of membership of the other credit union.

IV.C—NCUA's Procedures for Amending the Field of Membership

IV.C.1—General

All requests for approval to amend a federal credit union's charter must be submitted to the Office of Consumer Financial Protection and Access Director.

IV.C.2—Office of Consumer Financial Protection and Access Director Decision

NCUA staff will review all amendment requests in order to ensure conformance to NCUA policy.

Before acting on a proposed amendment, the Office of Consumer Financial Protection

and Access Director may require an on-site review. In addition, the Office of Consumer Financial Protection and Access Director may, after taking into account the significance of the proposed field of membership amendment, require the applicant to submit a business plan addressing specific issues.

The financial and operational condition of the requesting credit union will be considered in every instance. An expanded field of membership may provide the basis for reversing adverse trends. In such cases, an amendment to expand the field of membership may be granted notwithstanding the credit union's adverse trends. The applicant credit union must clearly establish that the approval of the expanded field of membership meets the requirements of Section IV.B.2 of this Chapter and will not increase the risk to the NCUSIF.

IV.C.3—Office of Consumer Financial Protection and Access Director Approval

If the Office of Consumer Financial Protection and Access Director approves the requested amendment, the credit union will be issued an amendment to Section 5 of its charter.

IV.C.4—Office of Consumer Financial Protection and Access Director Disapproval

When the Office of Consumer Financial Protection and Access Director disapproves any application, in whole or in part, to amend the field of membership under this chapter, the applicant will be informed in writing of the:

- Specific reasons for the action;
-
- Options to consider, if appropriate, for gaining approval; and
- Appeal procedure.

IV.C.5—Appeal of Office of Consumer Financial Protection and Access Director Decision

If a field of membership expansion request, merger, or spin-off is denied by staff, the federal credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial and must be clearly identified as such and address the reason(s) the federal credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access or, as applicable, the appropriate regional office or Office of National Examinations and Supervision Director. NCUA central office staff will make an independent review of the facts and present the appeal to the NCUA Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the office rendering the initial decision for reconsideration. A reconsideration will contain new and material evidence addressing the reasons for the initial denial. The office rendering the initial decision will have 30 days from the date of the receipt of the request for reconsideration to make a final decision. If the request is again denied, the applicant may proceed with the appeal process within 60 days of the date of the last denial. A second request for reconsideration will be treated as an appeal to the NCUA Board.

IV.D—Mergers, Purchase and Assumptions, and Spin-Offs

In general, other than the addition of select groups, there are three additional ways a multiple common bond federal credit union can expand its field of membership:

- By taking in the field of membership of another credit union through a merger;
- By taking in the field of membership of another credit union through a purchase and assumption (P&A); or
- By taking a portion of another credit union's field of membership through a spin-off.

IV.D. Voluntary Mergers

a. All Select Groups in the Merging Credit Union's Field of Membership Have Less Than 3,000 Primary Potential Members

A voluntary merger of two or more federal credit unions is permissible as long as each select group in the merging credit union's field of membership has less than 3,000 primary potential members. While the merger requirements outlined in Section 205 of the Federal Credit Union Act must still be met, the requirements of Chapter 2, Section IV.B.2 of this manual are not applicable.

b. One or More Select Groups in the Merging Credit Union's Field of Membership Has 3,000 or More Primary Potential Members

If the merging credit unions serve the same group, and the group consists of 3,000 or more primary potential members, then the ability to form a separate credit union analysis is not required for that group. If the merging credit union has any other groups consisting of 3,000 or more primary potential members, special requirements apply. NCUA will analyze each group of 3,000 or more primary potential members, except as noted above, to determine whether the formation of a separate credit union by such a group is practical. If the formation of a separate credit union by such a group is not practical because the group lacks sufficient volunteer and other resources to support the efficient and effective operations of a credit union or does not meet the economic advisable criteria outlined in Chapter 1, the group may be merged into a multiple common bond credit union. If the formation of a separate credit union is practical, the group must be spun-off before the merger can be approved.

c. Merger of a Single Common Bond Credit Union Into a Multiple Common Bond Credit Union

A financially healthy single common bond credit union with a primary potential membership of 3,000 or more cannot merge into a multiple common bond credit union, absent supervisory reasons, unless the continuing credit union already serves the same group.

d. Merger Approval

If the merger is approved, the qualifying groups within the merging credit union's field of membership will be transferred intact to the continuing credit union and can continue to be served.

Where the merging credit union is state-chartered, the field of membership rules applicable to a federal credit union apply.

Mergers must be approved by the applicable NCUA regional or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union, and, as applicable, the state regulators.

IV.D.2—Supervisory Mergers

The NCUA may approve the merger of any federally insured credit union when safety and soundness concerns are present without regard to the 3,000 numerical limitation. The credit union need not be insolvent or in danger of insolvency for NCUA to use this statutory authority. Examples constituting appropriate reasons for using this authority are: abandonment of the management and/or officials and an inability to find replacements, loss of sponsor support, serious and persistent record-keeping problems, sustained material decline in financial condition, or other serious or persistent circumstances.

IV.D. Emergency Mergers

An emergency merger may be approved by NCUA without regard to common bond or other legal constraints. An emergency merger involves NCUA's direct intervention and approval. The credit union to be merged must either be insolvent or in danger of insolvency, as defined in the Glossary, and NCUA must determine that:

- An emergency requiring expeditious action exists;
- Other alternatives are not reasonably available; and
- The public interest would best be served by approving the merger.

If not corrected, conditions that could lead to insolvency include, but are not limited to:

- Abandonment by management;
- Loss of sponsor;
- Serious and persistent record-keeping problems; or
- Serious and persistent operational concerns.

In an emergency merger situation, NCUA will take an active role in finding a suitable merger partner (continuing credit union). NCUA is primarily concerned that the continuing credit union has the financial strength and management expertise to absorb the troubled credit union without adversely affecting its own financial condition and stability.

As a stipulated condition to an emergency merger, the field of membership of the merging credit union may be transferred intact to the continuing federal credit union without regard to any field of membership restrictions including numerical limitation requirements. Under this authority, any single occupational or associational common bond, multiple common bond, or community charter may merger into a multiple common bond credit union and that credit union can continue to serve the merging credit union's field of membership. Subsequent field of membership expansions of the continuing

multiple common bond credit union must be consistent with multiple common bond policies.

Emergency mergers involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union and, as applicable, the state regulators.

IV.D. Purchase and Assumption (P&A)

Another alternative for acquiring the field of membership of a failing credit union is through a consolidation known as a P&A. Generally, the requirements applicable to field of membership expansions found in this chapter apply to purchase and assumptions where the purchasing credit union is a federal charter.

A P&A has limited application because, in most cases, the failing credit union must be placed into involuntary liquidation. However, in the few instances where a P&A may occur, the assuming federal credit union, as with emergency mergers, may acquire the entire field of membership if the emergency criteria are satisfied. Specified loans, shares, and certain other designated assets and liabilities, without regard to field of membership restrictions, may also be acquired without changing the character of the continuing federal credit union for purposes of future field of membership amendments. Subsequent field of membership expansions must be consistent with multiple common bond policies.

P&As involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the purchased and/or assumed credit union and, as applicable, the state regulators.

IV.D.5—Spin-Offs

A spin-off occurs when, by agreement of the parties, a portion of the field of membership, assets, liabilities, shares, and capital of a credit union are transferred to a new or existing credit union. A spin-off is unique in that usually one credit union has a field of membership expansion and the other loses a portion of its field of membership.

All common bond requirements apply regardless of whether the spun-off group becomes a new charter or goes to an existing federal charter.

The request for approval of a spun-off group must be supported with a plan that addresses, at a minimum:

- Why the spin-off is being requested;
- What part of the field of membership is to be spun off;
- Which assets, liabilities, shares, and capital are to be transferred;
- The financial impact the spin-off will have on the affected credit unions;
- The ability of the acquiring credit union to effectively serve the new members;
- The proposed spin-off date; and
- Disclosure to the members of the requirements set forth above.

The spin-off request must also include current financial statements from the affected credit unions and the proposed voting ballot.

For federal credit unions spinning off a group, membership notice and voting requirements and procedures are the same as for mergers (see part 708 of the NCUA Rules and Regulations), except that only the members directly affected by the spin-off—those whose shares are to be transferred—are permitted to vote. Members whose shares are not being transferred will not be afforded the opportunity to vote. All members of the group to be spun off (whether they voted in favor, against, or not at all) will be transferred if the spin-off is approved by the voting membership. Voting requirements for federally insured state credit unions are governed by state law.

Spin-offs involving federally insured credit unions in different NCUA regions must be approved by all regional directors and, if applicable, the Office of National Examinations and Supervision Director where the credit unions are headquartered and the state regulators, as applicable. Spin-offs in the same region also require approval by the state regulator, as applicable.

IV.E—Overlaps

IV.E.1—General

An overlap exists when a group of persons is eligible for membership in two or more credit unions, including state charters. An overlap is permitted when the expansion's beneficial effect in meeting the convenience and needs of the members of the group proposed to be included in the field of membership outweighs any adverse effect on the overlapped credit union.

Credit unions must investigate the possibility of an overlap with federally insured credit unions prior to submitting an expansion request if the group has 5,000 or more primary potential members. If cases arise where the assurance given to the Office of Consumer Financial Protection and Access Director concerning the unavailability of credit union service is inaccurate, the misinformation may be grounds for removal of the group from the federal credit union's charter.

When an overlap situation requiring analysis does arise, officials of the expanding credit union must ascertain the views of the overlapped credit union. If the overlapped credit union does not object, the applicant must submit a letter or other documentation to that effect. If the overlapped credit union does not respond, the expanding credit union must notify NCUA in writing of its attempt to obtain the overlapped credit union's comments.

NCUA will approve an overlap if the expansion's beneficial effect in meeting the convenience and needs of the members of the group outweighs any adverse effect on the overlapped credit union.

In reviewing the overlap, the Office of Consumer Financial Protection and Access Director will consider:

- The view of the overlapped credit union(s);
- Whether the overlap is incidental in nature—the group of persons in question is so small as to have no material effect on the original credit union;
- Whether there is limited participation by members or employees of the group in the original credit union after the expiration of a reasonable period of time;
- Whether the original credit union fails to provide requested service;
- Financial effect on the overlapped credit union;
- The desires of the group(s);
- The desire of the sponsor organization; and
- The best interests of the affected group and the credit union members involved.

Generally, if the overlapped credit union does not object, and NCUA determines that there is no safety and soundness problem, the overlap will be permitted.

Potential overlaps of a federally insured state credit union's field of membership by a federal credit union will generally be analyzed in the same way as if two federal credit unions were involved. Where a federally insured state credit union's field of membership is broadly stated, NCUA will exclude its field of membership from any overlap protection.

NCUA will permit multiple common bond federal credit unions to overlap community charters without performing an overlap analysis.

IV.E. Overlap Issues as a Result of Organizational Restructuring

A federal credit union's field of membership will always be governed by the field of membership descriptions contained in Section 5 of its charter. Where a sponsor organization expands its operations internally, by acquisition or otherwise, the credit union may serve these new entrants to its field of membership if they are part of any select group listed in Section 5. Where acquisitions are made which add a new subsidiary, the group cannot be served until the subsidiary is included in the field of membership through a housekeeping amendment.

A federal credit union's field of membership will always be governed by the field of membership descriptions contained in Section 5 of its charter. Where a sponsor organization expands its operations internally, by acquisition or otherwise, the credit union may serve these new entrants to its field of membership if they are part of any select group listed in Section 5. Where acquisitions are made which add a new subsidiary, the group cannot be served until the subsidiary is included in the field of membership through a housekeeping amendment.

Overlaps may occur as a result of restructuring or merger of the parent organization. When such overlaps occur, each credit union must request a field of membership amendment to reflect the new groups each wishes to serve. The credit union can continue to serve any current group in its field of membership that is acquiring a new group or has been acquired by a new group.

The new group cannot be served by the credit union until the field of membership amendment is approved by NCUA.

Credit unions affected by organizational restructuring or merger should attempt to resolve overlap issues among themselves. Unless an agreement is reached limiting the overlap resulting from the corporate restructuring, NCUA will permit a complete overlap of the credit unions' fields of membership. When two groups merge, or one group is acquired by the other, and each is in the field of membership of a credit union, both (or all affected) credit unions can serve the resulting merged or acquired group, subject to any existing geographic limitation and without regard to any overlap provisions. This is accomplished through a housekeeping amendment.

Credit unions must submit to NCUA documentation explaining the restructuring and provide information regarding the new organizational structure.

IV.E.3—Exclusionary Clauses

An exclusionary clause is a limitation precluding the credit union from serving the primary members of a portion of a group otherwise included in its field of membership. NCUA no longer grants exclusionary clauses. Those granted prior to the adoption of this new Chartering and Field of Membership Manual will remain in effect unless the credit unions agree to remove them or one of the affected credit unions submits a housekeeping amendment to have it removed.

IV.F—Charter Conversion

A multiple common bond federal credit union may apply to convert to a community charter provided the field of membership requirements of the community charter are met. Groups within the existing charter which cannot qualify in the new charter cannot be served except for members of record, or groups or communities obtained in an emergency merger or P&A. A credit union must notify all groups that will be removed from the field of membership as a result of conversion. Members of record can continue to be served. Also, in order to support a case for a conversion, the applicant federal credit union may be required to develop a detailed business plan as specified in Chapter 2, Section V.A.3.

A multiple common bond federal credit union may apply to convert to a single occupational or associational common bond charter provided the field of membership requirements of the new charter are met. Groups within the existing charter, which do not qualify in the new charter, cannot be served except for members of record, or groups or communities obtained in an emergency merger or P&A. A credit union must notify all groups that will be removed from the field of membership as a result of conversion.

IV.G—Credit Union Requested Removal of Groups From the Field of Membership

A credit union may request removal of a group from its field of membership for various reasons. The most common reasons for this type of amendment are:

- The group is within the field of membership of two credit unions and one wishes to discontinue service;
- The federal credit union cannot continue to provide adequate service to the group;
- The group has ceased to exist;
- The group does not respond to repeated requests to contact the credit union or refuses to provide needed support;
- The group initiates action to be removed from the field of membership; or
- The federal credit union wishes to convert to a single common bond.

When a federal credit union requests an amendment to remove a group from its field of membership, the Office of Consumer Financial Protection and Access Director will determine why the credit union desires to remove the group. If the Office of Consumer Financial Protection and Access Director concurs with the request, membership will continue for those who are already members under the ''once a member, always a member'' provision of the Federal Credit Union Act.

IV.H—NCUA Supervisory Action To Remove Groups From the Field of Membership

NCUA has in place quality control processes that protect the integrity of its field of membership requirements. As part of this obligation, NCUA's Office of Consumer Financial Protection and Access will randomly select groups added through NCUA's Field of Membership Internet Application (FOMIA) system for quality assurance reviews even if the expansion application meets all the conditions for approval. Each FCU is responsible for obtaining certain documentation when seeking to add groups to its field of membership through FOMIA. In addition, as indicated in the FOMIA User Instruction Guide, available on NCUA's Web site, an FCU must permanently retain the documentation from the select group requesting service and the Confirmation Certificate generated at the time the FOMIA request is submitted to NCUA.

As part of the quality assurance process, the Office of Consumer Financial Protection and Access reserves the right to request this documentation at any time. If the FCU fails to provide this documentation when the Office of Consumer Financial Protection and Access requests it, the director of the Office of Consumer Financial Protection and Access may consider removing the group from the FCU's field of membership and restricting the FCU from using the FOMIA system for future requests. Specifically, as part of the FOMIA quality assurance process, the Office of Consumer Financial Protection and Access staff will do the following:

1. Within 10 days of receiving an application selected for a quality assurance review, notify the FCU of the documentation the Office of Consumer Financial Protection and Access requires. The FCU will have 15 days to provide the necessary documentation. the Office of Consumer Financial Protection and Access will respond to the FCU with a determination on the quality assurance review of the association within 15 days of receiving the requested information;

2. After receiving the additional documentation, if any concerns remain outstanding, the Office of Consumer Financial Protection and Access will again correspond with the FCU and provide a 15-day time frame for correcting the concern. the Office of Consumer Financial Protection and Access will respond to the FCU with a determination on the quality assurance review of the association within 15 days of receiving the requested information; and

3. If the FCU does not provide the requested documentation, or cannot correct the concern, the Office of Consumer Financial Protection and Access Director will deny the application and notify the credit union of its appeal rights.

IV.I—NCUA Investigation of Potential Field of Membership Violations

NCUA's Office of Consumer Financial Protection and Access is responsible for investigating field of membership complaints from the public, and matters referred to it from the field. It also pursues corrective action as needed for FCUs with confirmed field of membership violations. Although circumstances can vary with each case, the Office of Consumer Financial Protection and Access will generally adhere to the following process for investigating and addressing potential field of membership violations:

1. Initially correspond with management to outline concerns and request clarifying information within 60 days. the Office of Consumer Financial Protection and Access will also provide context as to the source of NCUA's concerns, such as the discovery of new information about a particular group or an examination finding brought to the attention of the Office of Consumer Financial Protection and Access;

2. If the Office of Consumer Financial Protection and Access does not receive the requested information within 60 days, it will notify the FCU and again request the required information be provided within 30 days;

3. After receiving the additional documentation, if any concerns remain outstanding, the Office of Consumer Financial Protection and Access will again correspond with the FCU to provide a 60-day time frame for addressing the concern; and

4. If the FCU is unable to correct the concern, and after consultation with the Office of General Counsel and the appropriate Regional Office or Office of National Examinations and Supervision Director, and in accordance with agency guidelines for administrative actions, the Director of the Office of Consumer Financial Protection and Access will remove the group from the FCU's field of membership pursuant to authority delegated by the NCUA Board. Removal of a group is treated the same as an initial denial under the Chartering Manual. In any adverse final determination on removal under the above delegations, the Office of Consumer Financial Protection and Access will notify the FCU of its appeal rights.

NCUA considers the removal of an association from an FCU's field of membership as an action of last resort. If a group is removed, the FCU can no longer add new members from the group, but can

continue serving those who are already members of the FCU under the ''once a member, always a member'' provision of the Federal Credit Union Act. Also, if the group subsequently qualifies due to changes to the group itself, management can submit a new application at that time.

IV.J—Other Persons Eligible for Credit Union Membership

A number of persons, by virtue of their close relationship to a common bond group, may be included, at the charter applicant's option, in the field of membership. These include the following:

- Spouses of persons who died while within the field of membership of this credit union;
- Employees of this credit union;
- Persons retired as pensioners or annuitants from the above employment;
- Volunteers;
- Members of the immediate family or household;
- Honorably discharged veterans who served in any of the Armed Services of the United States in this charter;
- Organizations of such persons; and
- Corporate or other legal entities in this charter.

Immediate family is defined as spouse, child, sibling, parent, grandparent, or grandchild. This includes stepparents, stepchildren, stepsiblings, and adoptive relationships.

Household is defined as persons living in the same residence maintaining a single economic unit.

Membership eligibility is extended only to individuals who are members of an ''immediate family or household'' of a credit union member. It is not necessary for the primary member to join the credit union in order for the immediate family or household member of the primary member to join, provided the immediate family or household clause is included in the field of membership. However, it is necessary for the immediate family member or household member to first join in order for that person's immediate family member or household member to join the credit union. A credit union can adopt a more restrictive definition of immediate family or household.

Volunteers, by virtue of their close relationship with a sponsor group, may be included. Examples include volunteers working at a hospital or church.

Under the Federal Credit Union Act, once a person becomes a member of the credit union, such person may remain a member of the credit union until the person chooses to withdraw or is expelled from the membership of the credit union. This is commonly referred to as ''once a member, always a member.'' The ''once a member, always a member'' provision does not prevent a credit union from restricting services to members who are no longer within the field of membership

V—Community Charter Requirements

V.A.1—General

There are two types of community charters. One is based on a single, geographically well-defined local community or neighborhood; the other is a rural district. More than one credit union may serve the same community.

NCUA recognizes four types of affinity on which both a community charter and a rural district can be based—persons who live in, worship in, attend school in, or work in the community or rural district. Businesses and other legal entities within the community boundaries or rural district may also qualify for membership.

NCUA has established the following requirements for community charters:

- The geographic area's boundaries must be clearly defined; and
- The area is a well-defined local community or a rural district.

V.A.2—Definition of Well-Defined Local Community and Rural District

In addition to the documentation requirements in Chapter 1 to charter a credit union, a community credit union applicant must provide additional documentation addressing the proposed area to be served and community service policies.

An applicant has the burden of demonstrating to NCUA that the proposed community area meets the statutory requirements of being: (1) Well-defined, and (2) a local community or rural district.

''Well-defined'' means the proposed area has specific geographic boundaries. Geographic boundaries may include a city, township, county (single, multiple, or portions of a county) or a political equivalent, school district, or a clearly identifiable neighborhood. Although state boundaries are well-defined areas, states themselves do not meet the requirement that the proposed area be a local community.

The well-defined local community requirement is met if:

- Single Political Jurisdiction—The area to be served is in a recognized Single Political Jurisdiction, *i.e.,* a city, county, or their political equivalent, or any individual portion thereof.
- Statistical Area—The area is a designated Core Based Statistical Area or allowing a portion thereof, or in the case of a Core Based Statistical Area with Metropolitan Divisions, the area is a Metropolitan Division or is a portion thereof; or
- The area is a designated a Combined Statistical Area or a portion thereof; AND
- The Core Based Statistical Area, Metropolitan Division or Combined Statistical Area, or the portion thereof, must have a population of 2.5 million or less people.
- Compelling Evidence of Interaction or Common Interests—In lieu of a statistical area as defined above, this option applies only to the addition of an immediately adjacent area falling outside a Single Political Jurisdiction, Core Based Statistical Area or Combined Statistical Area, and thus may demonstrate a sufficient level of interaction to qualify as a local community. For these situations, applicants have the option of submitting a narrative to NCUA to address how the residents meet the requirements for being a local community. The Office of Consumer Financial Protection and Access will issue additional guidance to help a credit union develop its written narrative. NCUA will base its decision on a consideration of the following factors with respect to the proposed service area in its entirety:

Economic Hub: Evidence indicates residents commonly travel to a geographically compact locale within the area for work and major commerce needs. Traffic flows, the presence of common or related industries, or unified economic planning demonstrate how the locales have economic interdependence.

Population Center: Area has a dominant county or municipality with a significant portion of the area's population and evidence exists to support the relevance of the population center to all residents within the area.

Isolated Areas: Areas geographically isolated, such as by mountains, bodies of water, or other prominent features.

Quasi-Governmental Agencies: A quasi-governmental agency, such as a regional planning commission, predominantly covers the proposed service area and derives its leadership from the area to advance meaningful objectives advancing the residents' common interests in economic development and/or improving quality of life. Success of agency in meeting its mission depends upon collaboration from throughout the area.

Government Designations: A division of a federal or state agency specifically designates the proposed service area as its area of coverage or as a target area for specific programs.

Shared Public Services/Facilities: Formal agreements exist that provide for a common need shared by all of the residents, such as common police or fire protection, or public utilities.

Colleges and Universities: Evidence exists to demonstrate the common relevance of an institution or institutions to the entire area, such as unique educational initiatives to support economic objectives benefiting all residents and/or partnerships with local businesses or high schools.

An area of any geographic size qualifies as a Rural District if:

- The proposed district has well-defined, contiguous geographic boundaries;
- The total population of the proposed district does not exceed 1,000,000.
- Either more than 50% of the proposed district's population resides in census blocks or other geographic units that are designated as rural by either the Consumer Financial Protection Bureau or the United States Census Bureau, OR the district has a population density of 100 persons or fewer per square mile; and
- The boundaries of the well-defined rural district do not exceed the outer boundaries of the states that are *immediately contiguous* to the state in which the credit union maintains its headquarters (*i.e.,* not to exceed the outer perimeter of the layer of states immediately surrounding the headquarters state).

The affinity groups that apply to well-defined local communities, found in Chapter 2, Section V.G., also apply to Rural Districts.

The OMB definitions of Core Based Statistical Area and Metropolitan Division, as

well as that of Combined Statistical Area (found at *https://www.whitehouse.gov/omb/bulletins_default*) are incorporated herein by reference. Access to these definitions is also available through NCUA's Web site at *http://www.ncua.gov*.

The requirements in Chapter 2, Sections V.A.4 through V.G. also apply to a credit union that serves a rural district.

V.A.3—Previously Approved Communities

If NCUA has determined that a specific geographic area is a well-defined local community, then a new applicant need not reestablish that fact as part of its application to serve the exact area. The new applicant must, however, note NCUA's previous determination as part of its overall application. An applicant applying for an area that is not exactly the same as a previously approved well defined local community must comply with the current criteria in place for determining a well-defined local community.

V.A. Business Plan Requirements for a Community Credit Union

A community credit union is frequently more susceptible to competition from other local financial institutions and generally does not have substantial support from any single sponsoring company or association. As a result, a community credit union will often encounter financial and operational factors that differ from an occupational or associational charter. Its diverse membership may require special marketing programs targeted to different segments of the community. For example, the lack of payroll deduction creates special challenges in the development and promotion of savings programs and in the collection of loans. Accordingly, to support an application for a community charter, an applicant Federal credit union must develop a business plan incorporating the following data:

- Pro forma financial statements for a minimum of 24 months after the proposed conversion, including the underlying assumptions and rationale for projected member, share, loan, and asset growth;
- Anticipated financial impact on the credit union, including the need for additional employees and fixed assets, and the associated costs;
- A description of the current and proposed office/branch structure, including a general description of the location(s); parking availability, public transportation availability, drive-through service, lobby capacity, or any other service feature illustrating community access;
- A marketing plan addressing how the community will be served for the 24-month period after the proposed conversion to a community charter, including detailing: How the credit union will implement its business plan; the unique needs of the various demographic groups in the proposed community; how the credit union will market to each group, particularly underserved groups; which community-based organizations the credit union will target in its outreach efforts; the credit union's marketing budget projections dedicating greater resources to reaching new members; and the credit union's timetable for implementation, not just a calendar of events;
- Details, terms and conditions of the credit union's financial products, programs, and services to be provided to the entire community; and
- Maps showing the current and proposed service facilities, ATMs, political boundaries, major roads, and other pertinent information.

An existing Federal credit union may apply to convert to a community charter. Groups currently in the credit union's field of membership, but outside the new community credit union's boundaries, may not be included in the new community charter. Therefore, the credit union must notify groups that will be removed from the field of membership as a result of the conversion. Members of record can continue to be served.

Before approval of an application to convert to a community credit union, NCUA must be satisfied that the credit union will be viable and capable of providing services to its members.

Community credit unions will be expected to regularly review and to follow, to the fullest extent economically possible, the marketing and business plans submitted with their applications. Additionally, NCUA will follow-up with an FCU every year for three years after the FCU has been granted a new or expanded community charter, and at any other intervals NCUA believes appropriate, to determine if the FCU is satisfying the terms of its marketing and business plans.

An FCU failing to satisfy those terms will be subject to supervisory action. As part of this review process, the regional office or Office of National Examinations and Supervision Director will report to the NCUA Board instances where an FCU is failing to satisfy the terms of its marketing and business plan and indicate what supervisory actions the region or ONES intends to take.

V.A.5—Community Boundaries

The geographic boundaries of a community Federal credit union are the areas defined in its charter. The boundaries can usually be defined using political borders, streets, rivers, railroad tracks, or other static geographical feature.

A community that is a recognized legal entity may be stated in the field of membership— for example, ''Gus Township, Texas,'' ''Isabella City, Georgia,'' or ''Fairfax County, Virginia.''

A community that is an entire United States Census Bureau designated Core Based Statistical Area or Combined Statistical Area may be stated in the field of membership— for example, ''Fort Wayne, IN Metropolitan Statistical Area,'' ''Albany, GA Metropolitan Statistical Area,'' or ''Syracuse-Auburn, NY Combined Statistical Area.''

V.A.6—Special Community Charters

A community field of membership may include persons who work or attend school in a particular industrial park, shopping mall, office building or complex, or similar development. The proposed field of membership must have clearly defined geographic boundaries.

V.A. Ample Community Fields of Membership

A community charter does not have to include all four affinities (*i.e.,* live, work, worship, or attend school in a community). Some examples of community fields of membership are:

- Persons who live, work, worship, or attend school in, and businesses located in the area of Johnson City, Tennessee, bounded by Fern Street on the north, Long Street on the east, Fourth Street on the south, and Elm Avenue on the west;
- Persons who live or work in Green County, Maine;
- Persons who live, worship, work (or regularly conduct business in), or attend school on the University of Dayton campus, in Dayton, Ohio;
- Persons who work for businesses located in Clifton Country Mall, in Clifton Park, New York;
- Persons who live, work, or worship in the Binghamton, New York, Core Based Statistical Area, consisting of Broome and Tioga Counties, New York (a qualifying Core Based Statistical Area in its entirety);
- Persons who live, work, worship, or attend school in the portion of the Oklahoma City, OK Metropolitan Statistical Area that includes Canadian and Oklahoma counties, Oklahoma (two contiguous counties in a portion of a qualifying Core Based Statistical Area that has seven counties in total); or
- Persons who live, work, worship, or attend school in Uinta County or Lincoln County, Wyoming, a rural district.

Some examples of insufficiently defined local communities, neighborhoods, or rural districts are:

- Persons who live or work within and businesses located within a ten-mile radius of Washington, DC (not a permitted community);
- Persons who live or work in the industrial section of New York, New York. (not well- defined nor a permitted community); or
- Persons who live or work in the greater Boston area. (not well-defined).

Some examples of unacceptable local communities, neighborhoods, or rural districts are:

- Persons who live or work in the State of California. (not a permitted community). Persons who live in the first congressional district of Florida. (not a permitted community).

V.B—Field of Membership Amendments

A community credit union may amend its field of membership by adding additional affinities or removing exclusionary clauses. This can be accomplished with a housekeeping amendment.

A community credit union also may expand its geographic boundaries. Persons who live, work, worship, or attend school within the proposed well-defined local community, neighborhood or rural district must have common interests and/or interact. The credit union must follow the requirements of Section V.A.4 of this chapter.

A community credit union that is based on a Single Political Jurisdiction, a Statistical Area (*e.g.,* Core Based Statistical Area or

Combined Statistical Area) or a rural district may expand its geographic boundaries to add a bordering area, provided the area is well defined and the credit union demonstrates that persons who live, work, worship, or attend school within the proposed expanded community (*i.e.,* on both sides of the boundary separating the existing community and the bordering area) have common interests and/or interact. Such a credit union applying to expand its geographic boundaries to add a bordering area must follow a streamlined version of the business plan requirements of Section V.A.4 of this chapter and the expanded community would be subject to the corresponding population limit—2.5 million in the case of a Single Political Jurisdiction, or a Statistical Area and 1 million in the case of a rural district. The streamlined business plan requirements for adding a bordering area are:

- Anticipated marginal financial impact on the credit union of adding the proposed bordering area, including the need for additional employees and fixed assets, and the associated costs;
- A description of the current and, if applicable, proposed office/branch structure specific to serving the proposed bordering area;
- A marketing plan addressing how the new community will be served for the 24-month period after the proposed expansion of a community charter, including detailing how the credit union will address the unique needs of any demographic groups in the proposed bordering community not presently served by the credit union and how the credit union will market to any new groups; and
- Details, terms and conditions of any new financial products, programs, and services to be introduced as part of this expansion.

V.C—NCUA Procedures for Amending the Field of Membership

V.C.1—General

All requests for approval to amend a community credit union's charter must be submitted to the Office of Consumer Financial Protection and Access Director. If a decision cannot be made within a reasonable period of time, the Office of Consumer Financial Protection and Access Director will notify the credit union.

V.C.2—NCUA's Decision

The financial and operational condition of the requesting credit union will be considered in every instance. The economic advisability of expanding the field of membership of a credit union with financial or operational problems must be carefully considered.

In most cases, field of membership amendments will only be approved for credit unions that are operating satisfactorily. Generally, if a federal credit union is having difficulty providing service to its current membership, or is experiencing financial or other operational problems, it may have more difficulty serving an expanded field of membership.

Occasionally, however, an expanded field of membership may provide the basis for reversing current financial problems. In such cases, an amendment to expand the field of membership may be granted notwithstanding the credit union's financial or operational problems. The applicant credit union must clearly establish that the expanded field of membership is in the best interest of the members and will not increase the risk to the NCUSIF.

V.C.3—NCUA Approval

If the requested amendment is approved by NCUA, the credit union will be issued an amendment to Section 5 of its charter.

V.C.4—NCUA Disapproval

When NCUA disapproves any application to amend the field of membership, in whole or in part, under this chapter, the applicant will be informed in writing of the:

- Specific reasons for the action;
- If appropriate, options or suggestions that could be considered for gaining approval; and
- Appeal procedures.

V.C.5—Appeal of Office of Consumer Financial Protection and Access Director Decision

If a field of membership expansion request, merger, or spin-off is denied by staff, the federal credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial and must be clearly identified as such and address the specific reason(s) the federal credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access or, as applicable, the appropriate regional office or Office of National Examinations and Supervision Director. NCUA central office staff will make an independent review of the facts and present the appeal to the NCUA Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the office rendering the initial decision for reconsideration. A reconsideration will contain new and material evidence addressing the reasons for the initial denial. The office rendering the initial decision will have 30 days from the date of the receipt of the request for reconsideration to make a final decision. If the request is again denied, the applicant may proceed with the appeal process within 60 days of the date of the last denial. A second request for reconsideration will be treated as an appeal to the NCUA Board.

V. D—Mergers, Purchase and Assumptions, and Spin-Offs

There are three additional ways a community federal credit union can expand its field of membership:

- By taking in the field of membership of another credit union through a merger;
- By taking in the field of membership through a purchase and assumption (P&A); or
- By taking a portion of another credit union's field of membership through a spin-off.

V.D. Mergers

Generally, the requirements applicable to field of membership expansions apply to mergers where the continuing credit union is a community federal charter.

Where both credit unions are community charters, the continuing credit union must meet the criteria for expanding the community boundaries. A community credit union cannot merge into a single occupational/associational, or multiple common bond credit union, except in an emergency merger. However, a single occupational or associational, or multiple common bond credit union can merge into a community charter as long as the merging credit union has a service facility within the community boundaries or a majority of the merging credit union's field of membership would qualify for membership in the community charter. While a community charter may take in an occupational, associational, or multiple common bond credit union in a merger, it will remain a community charter.

Groups within the merging credit union's field of membership located outside of the community boundaries may not continue to be served. The merging credit union must notify groups that will be removed from the field of membership as a result of the merger. However, the credit union may continue to serve members of record.

Where a state-chartered credit union is merging into a community federal credit union, the continuing federal credit union's field of membership will be worded in accordance with NCUA policy. Any subsequent field of membership expansions must comply with applicable amendment procedures.

Mergers must be approved by the NCUA regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union, and, as applicable, the state regulators.

V.D. Emergency Mergers

An emergency merger may be approved by NCUA without regard to common bond or other legal constraints. An emergency merger involves NCUA's direct intervention and approval. The credit union to be merged must either be insolvent or in danger of insolvency, as defined in the Glossary, and NCUA must determine that:

- An emergency requiring expeditious action exists;
- Other alternatives are not reasonably available; and
- The public interest would best be served by approving the merger.

If not corrected, conditions that could lead to insolvency include, but are not limited to:

- Abandonment by management;
- Loss of sponsor;
- Serious and persistent record-keeping problems; or
- Serious and persistent operational concerns.

In an emergency merger situation, NCUA will take an active role in finding a suitable merger partner (continuing credit union). NCUA is primarily concerned that the continuing credit union has the financial

strength and management expertise to absorb the troubled credit union without adversely affecting its own financial condition and stability.

As a stipulated condition to an emergency merger, the field of membership of the merging credit union may be transferred intact to the continuing federal credit union without regard to any field of membership restrictions, including the service facility requirement. Under this authority, a federal credit union may take in any dissimilar field of membership.

Even though the merging credit union is a single common bond credit union or multiple common bond credit union or community credit union, the continuing credit union will remain a community charter. Future community expansions will be based on the continuing credit union's original community area.

Emergency mergers involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the merging credit union and, as applicable, the state regulators.

V.D. Purchase and Assumption (P&A)

Another alternative for acquiring the field of membership of a failing credit union is through a consolidation known as a P&A. Generally, the requirements applicable to community expansions found in this chapter apply to purchase and assumptions where the purchasing credit union is a federal charter.

A P&A has limited application because, in most instances, the failing credit union must be placed into involuntary liquidation. However, in the few instances where a P&A may occur, the assuming federal credit union, as with emergency mergers, may acquire the entire field of membership if the emergency criteria are satisfied.

In a P&A processed under the emergency criteria, specified loans, shares, and certain other designated assets and liabilities may also be acquired without regard to field of membership restrictions and without changing the character of the continuing federal credit union for purposes of future field of membership amendments.

If the P&A does not meet the emergency criteria, then only members of record can be obtained unless they otherwise qualify for membership in the community charter.

P&As involving federally insured credit unions in different NCUA regions must be approved by the regional director or Office of National Examinations and Supervision Director where the continuing credit union is headquartered, with the concurrence of the regional director or Office of National Examinations and Supervision Director of the purchased and/or assumed credit union and, as applicable, the state regulators.

V.D.4—Spin-Offs

A spin-off occurs when, by agreement of the parties, a portion of the field of membership, assets, liabilities, shares, and capital of a credit union are transferred to a new or existing credit union. A spin-off is unique in that usually one credit union has a field of membership expansion and the other loses a portion of its field of membership.

All field of membership requirements apply regardless of whether the spun-off group goes to a new or existing federal charter.

The request for approval of a spin-off must be supported with a plan that addresses, at a minimum:

- Why the spin-off is being requested;
- What part of the field of membership is to be spun off;
- Whether the field of membership requirements are met;
- Which assets, liabilities, shares, and capital are to be transferred;
- The financial impact the spin-off will have on the affected credit unions;
- The ability of the acquiring credit union to effectively serve the new members;
- The proposed spin-off date; and
- Disclosure to the members of the requirements set forth above.

The spin-off request must also include current financial statements from the affected credit unions and the proposed voting ballot.

For federal credit unions spinning off a portion of the community, membership notice and voting requirements and procedures are the same as for mergers (see part 708 of the NCUA Rules and Regulations), except that only the members directly affected by the spin-off—those whose shares are to be transferred—are permitted to vote. Members whose shares are not being transferred will not be afforded the opportunity to vote. All members of the group to be spun off (whether they voted in favor, against, or not at all) will be transferred if the spin-off is approved by the voting membership. Voting requirements for federally insured state credit unions are governed by state law.

V.E—Overlaps

V.E.1—General

Generally, an overlap exists when a group of persons is eligible for membership in two or more credit unions. NCUA will permit community credit unions to overlap any other charters without performing an overlap analysis.

V.E. Exclusionary Clauses

An exclusionary clause is a limitation precluding the credit union from serving the primary members of a portion of a group or community otherwise included in its field of membership.

NCUA no longer grants exclusionary clauses. Those granted prior to the adoption of this new Chartering and Field of Membership Manual will remain in effect unless the credit unions agree to remove them or one of the affected credit unions submits a housekeeping amendment to have it removed.

V.F—Charter Conversions

A community federal credit union may convert to a single occupational or associational, or multiple common bond credit union. The converting credit union must meet all occupational, associational, and multiple common bond requirements, as applicable. The converting credit union may continue to serve members of record of the prior field of membership as of the date of the conversion, and any groups or communities obtained in an emergency merger or P&A. A change to the credit union's field of membership and designated common bond will be necessary.

A community credit union may convert to serve a new geographical area provided the field of membership requirements of V.A.3 of this chapter are met. Members of record of the original community can continue to be served.

V.G—Other Persons With a Relationship to the Community

A number of persons who have a close relationship to the community may be included, at the charter applicant's option, in the field of membership. These include the following:

- Spouses of persons who died while within the field of membership of this credit union;
- Employees of this credit union;
- Volunteers in the community;
- Members of the immediate family or household; and
- Organizations of such persons

Immediate family is defined as spouse, child, sibling, parent, grandparent, or grandchild. This includes stepparents, stepchildren, stepsiblings, and adoptive relationships.

Household is defined as persons living in the same residence maintaining a single economic unit.

Membership eligibility is extended only to individuals who are members of an ''immediate family or household'' of a credit union member. It is not necessary for the primary member to join the credit union in order for the immediate family or household member of the primary member to join, provided the immediate family or household clause is included in the field of membership. However, it is necessary for the immediate family member or household member to first join in order for that person's immediate family member or household member to join the credit union. A credit union can adopt a more restrictive definition of immediate family or household.

Under the Federal Credit Union Act, once a person becomes a member of the credit union, such person may remain a member of the credit union until the person chooses to withdraw or is expelled from the membership of the credit union. This is commonly referred to as ''once a member, always a member.'' The ''once a member, always a member'' provision does not prevent a credit union from restricting services to members who are no longer within the field of membership.

Chapter 3—Low-Income Credit Unions and Credit Unions Serving Underserved Areas

I—Introduction

One of the primary reasons for the creation of federal credit unions is to make credit available to people of modest means for

provident and productive purposes. To help NCUA fulfill this mission, the agency has established special operational policies for federal credit unions that serve low-income groups and underserved areas. The policies provide a greater degree of flexibility that will enhance and invigorate capital infusion into low-income groups, low-income communities, and underserved areas. These unique policies are necessary to provide credit unions serving low-income groups with financial stability and potential for controlled growth and to encourage the formation of new charters as well as the delivery of credit union services in low-income communities.

II—Low-Income Credit Union

II.A—Defined

A credit union serving predominantly low-income members may be designated as a low-income credit union. Section 701.34 of NCUA's Rules and Regulations defines the term ''low- income members'' as those members:

- Who make less than 80 percent of the average for all wage earners as established by the Bureau of Labor Statistics; or
- Whose median family income falls at or below 80 percent of the median family income for the nation as established by the Census Bureau.

The term ''low-income members'' also includes members who are full-time or part-time students in a college, university, high school, or vocational school.

To obtain a low-income designation from NCUA, an existing credit union must establish that a majority of its members meet the low-income definition. An existing community credit union that serves a geographic area where a majority of residents meet the annual income standard is presumed to be serving predominantly low-income members. A low-income designation for a new credit union charter may be based on a majority of the potential membership.

II.B—Special Programs

A credit union with a low-income designation has greater flexibility in accepting nonmember deposits insured by the NCUSIF, are exempt from the aggregate loan limit on business loans, and may offer secondary capital accounts to strengthen its capital base. It also may participate in special funding programs such as the Community Development Revolving Loan Program for Credit Unions (CDRLP) if it is involved in the stimulation of economic development and community revitalization efforts.

The CDRLP provides both loans and grants for technical assistance to low-income credit unions. The requirements for participation in the revolving loan program are in part 705 of the NCUA Rules and Regulations. Only operating credit unions are eligible for participation in this program.

II.C—Low-Income Documentation

A federal credit union charter applicant or existing credit union wishing to receive a low- income designation should forward a separate request for the designation to the Office of Consumer Financial Protection and Access Director, along with appropriate documentation supporting the request.

For community charter applicants, the supporting material should include the median family income or annual wage figures for the community to be served. If this information is unavailable, the applicant should identify the individual zip codes or census tracts that comprise the community and NCUA will assist in obtaining the necessary demographic data.

Similarly, if single occupational or associational or multiple common bond charter applicants cannot supply income data on its potential members, they should provide the Office of Consumer Financial Protection and Access Director with a list which includes the number of potential members, sorted by their residential zip codes, and NCUA will assist in obtaining the necessary demographic data.

An existing credit union can perform a loan or membership survey to determine if the credit union is primarily serving low-income members.

II.D—Third-Party Assistance

A low-income federal credit union charter applicant may contract with a third party to assist in the chartering and low-income designation process. If the charter is granted, a low-income credit union may contract with a third party to provide necessary management services. Such contracts should not exceed the duration of one year subject to renewal.

II.E—Special Rules for Low-Income Federal Credit Unions

In recognition of the unique efforts needed to help make credit union service available to low-income groups, NCUA has adopted special rules that pertain to low-income credit union charters, as well as field of membership additions for low-income credit unions. These special rules provide additional latitude to enable underserved, low-income individuals to gain access to credit union service.

NCUA permits credit union chartering and field of membership amendments based on associational groups formed for the sole purpose of making credit union service available to low- income persons. The association must be defined so that all of its members will meet the low- income definition of Section 701.34 of the NCUA Rules and Regulations. Any multiple common bond credit union can add low-income associations to their fields of membership.

A low-income designated community federal credit union has additional latitude in serving persons who are affiliated with the community. In addition to serving members who live, work, worship, or attend school in the community, a low-income community federal credit union may also serve persons who participate in programs to alleviate poverty or distress, or who participate in associations headquartered in the community.

Examples of a low-income designated community and an associational-based low-income federal credit union are as follows:

- Persons who live in [the target area]; persons who work, worship, attend school, or participate in associations headquartered in [the target area]; persons participating in programs to alleviate poverty or distress which are located in [the target area]; incorporated and unincorporated organizations located in [the target area] or maintaining a facility in [the target area]; and organizations of such persons.
- Members of the Canarsie Economic Assistance League, in Brooklyn, NY, an association whose members all meet the low-income definition of Section 701.34 of the NCUA Rules and Regulations.

III—Service to Underserved Communities

III.A—General

A multiple common bond federal credit union may include in its field of membership, without regard to location, an ''underserved area'' as defined by the Federal Credit Union Act. 12

U.S.C. 1759(c)(2). The addition of an ''underserved area'' will not change the charter type of the multiple common bond federal credit union. More than one multiple common-bond federal credit union can serve the same ''underserved area,'' provided each credit union is approved as provided below.

By adding an ''underserved area,'' a multiple common bond federal credit union does not become eligible to receive the benefits afforded to low-income designated credit unions, such as expanded use of nonmember deposits and access to the Community Development Revolving Loan Program for Credit Unions.

III.B—''Underserved Area'' Defined

The Federal Credit Union Act defines an ''underserved area'' as (1) a ''local community, neighborhood, or rural district'' that (2) meets the definition of an ''investment area'' under section 103(16) of the Community Development Banking and Financial Institutions Act of 1994 (''CDFI''), 12 U.S.C. 4702(16), and (3) is ''underserved by other depository institutions'' based on data of the NCUA Board and the federal banking agencies.

III.B.1—Local Community

To be eligible for approval as ''underserved,'' a proposed area must be a well-defined local community, neighborhood, or rural district as defined in Chapter 2, sections V.A.1. and V.A.2. of this Manual.

III.B.2—Investment Area

To be approved as an ''underserved area,'' the proposed area must meet the CDFI definition of an ''investment area.'' *Id.* § 4702(16). A proposed area that, at the time the credit union applies, is designated in its entirety as an Empowerment Zone or Enterprise Community (*id.* § 1391) automatically qualifies as an ''investment area''; no further criteria of an ''investment area'' must be met. *Id.* § 4702(16)(B). A proposed area that is not designated as such must qualify as an ''investment area'' under ''the objective criteria of economic distress'' developed by the CDFI Fund (''distress criteria'') based on current decennial U.S. Census data, and also must have ''significant unmet needs'' for loans and financial services that credit unions are authorized to offer to their members. *Id.* § 4702(16)(A).

III.B.2. Economic Distress Criteria

Geographic Unit(s) By Proposed Area's Location. The location of a proposed ''underserved area'' either within or outside of a Metropolitan Statistical Area corresponding to the most recent completed decennial census published by the U.S. Bureau of the Census (''decennial Census'') determines the geographic unit(s) that apply to determine whether the area meets the distress criteria.

Within a Metropolitan Statistical Area. For a proposed area located, in whole or in part, within a Metropolitan Statistical Area, the permissible geographic units (''Metro units'') for implementing the economic distress criteria are: (i) A census tract; (ii) a block group; and (iii) an American Indian or Alaskan Native area. 12 CFR 1805.201(b)(3)(ii)(B) (2008). For ease of implementation, it is advisable to use a census tract as the proposed area's Metro unit.

Outside a Metropolitan Statistical Area. For a proposed area that is located entirely outside a Metropolitan Statistical Area, the permissible units (''Non-Metro units'') for implementing the economic distress criteria are: (i) A county or equivalent area; (ii) a minor civil division that is a unit of local government; (iii) an incorporated place; (iv) a census tract; (v) a block numbering area; (vi) a block group; and (vii) an American Indian or Alaskan Native area. *Id.* For ease of implementation, it is advisable to use either a census tract or county, as the case may be, as the proposed area's Non-Metro unit.

Proposed Area Consisting of a Single Metro Unit. A proposed area consisting of a single whole Metro unit (*e.g.,* a single census tract located within a Metropolitan Statistical Area) must meet one of the following distress criteria, as reported by the most recent decennial Census:

- *Unemployment.* The proposed area's unemployment rate is at least 1.5 times the national average; or
- *Poverty.* At least 20 percent (20%) of the proposed area's population lives in poverty; or
- *Median Family Income.* The proposed area's Median Family Income (''MFI'') is at or below 80 percent (80%) of either the MFI of the corresponding Metropolitan Statistical Area, or of the national MFI for Metro Areas, whichever is greater; or
- *Other Criterion.* Any other economic distress criterion the CDFI Fund may adopt in the future.

Id. § 1805.201(b)(3)(ii)(D)(1), (2)(i) and (3) (2008).

Proposed Area Consisting of a Single Non-Metro Unit. A proposed area consisting of a single whole Non-Metro unit (*e.g.,* a single county located outside a Metropolitan Statistical Area) must meet one of the following distress criteria, as reported by the most recent decennial Census:

- *Unemployment.* The proposed area's unemployment rate is at least 1.5 times the national average; or
- *Poverty.* At least 20 percent (20%) of the proposed area's population lives in poverty; or
- *Median Family Income.* The proposed area's MFI is at or below 80 percent (80%) of either the corresponding state's Non-Metro MFI or the national MFI for Non-Metro Areas, whichever is greater; or
- *Other Criterion.* Any other economic distress criterion the CDFI Fund may adopt in the future.

Id. § 1805.201(b)(3)(ii)(D)(1), (2)(ii) and (3) (2008). Alternatively, a proposed area consisting of a single Non-Metro county (located outside a Metropolitan Statistical Area) may instead meet either of the following two criteria, as reported by the decennial Census:

- *County Population Loss.* County's population loss of at least 10 percent (10%) between the most recent and the preceding decennial Census; or
- *County Migration Loss.* County's net migration loss of at least 5 percent (5%) in the 5- year period preceding the most recent decennial Census.

Id. § 1805.201(b)(3)(ii)(D)(4)–(5) (2008).

Proposed Area Consisting of Multiple Contiguous Units. When a proposed area consists of either multiple contiguous Metro units (*e.g.,* a group of adjoining census tracts) or multiple contiguous Non-Metro units (*e.g.,* a group of adjoining counties), a population threshold applies when implementing the economic distress criteria. At least 85 percent (85%) of the area's total population must reside within the units that are ''distressed,'' *i.e.,* that meet one of the applicable economic distress criteria above, as reported by the decennial Census (Unemployment, Poverty and MFI for census tracts plus, for counties only, Population Loss and Migration Loss); the balance of the area's population may reside in the non-''distressed'' tract(s). The population threshold is met, and the whole proposed area qualifies as ''distressed,'' when the ''distressed'' units represent at least 85 percent of the area's total population.

III.B.2.b—Proposed Area's ''Significant Unmet Needs''

A proposed area that is ''distressed'' also must display ''significant unmet needs'' for loans or for one or more of the financial services credit unions are authorized to offer. To meet this criterion, the credit union must include within its Business Plan a section, one page in length, entitled ''Significant Unmet Needs for Credit Union Services'' (''SUN section'') that establishes the existence of such unmet needs by identifying the credit and depository needs of the community and detailing how the credit union plans to serve those needs. The credit union may choose which among the following ''credit and depository needs'' to address in the SUN section: loans, share draft accounts, savings accounts, check cashing, money orders, certified checks, automated teller machines, deposit taking, safe deposit box services, and similar services. The existence of each ''credit and depository need'' the credit union identifies and plans to serve must be supported by objective reasons and/or accompanying documentation derived from an identified, authoritative source of the credit union's choice. Third-party documentation generally is the most compelling.

III.B.3—Underserved by Other Depository Institutions

A proposed area that meets the CDFI definition of an ''investment area'' (*i.e.,* is ''distressed'' and has ''significant unmet needs'') must also be underserved by other insured depository institutions, including credit unions. 12 U.S.C. 1759(c)(2)(A)(ii). This statutory criterion is met when the concentration of depository institution facilities among the population of the proposed area's non-''distressed'' tracts—which sets a benchmark level of adequate service—is greater than the concentration of facilities among the population of all of the proposed area's census tracts combined. This establishes the area's concentration of facilities ratio. If there are no non-''distressed'' tracts within a proposed area, a non-''distressed'' census tract or larger geographic unit (*e.g.,* city or county) of the credit union's choice that adjoins the proposed area may be used to set the benchmark concentration ratio.

Without regard to a proposed area's location within or outside a Metropolitan Statistical Area, this criterion compares two ratios: the ratio of facilities to the population of the non- ''distressed'' tracts (the benchmark) versus the same facilities-to-population ratio among all the tracts of the proposed area as a whole. If the benchmark ratio is greater than the ratio for the whole area, then the area is ''underserved by other depository institutions,'' and vice versa.

When, as the result of an initial Concentration of Facilities ratio calculation, a proposed area does not qualify as ''underserved by other depository institutions,'' NCUA will exclude non-depository banks (*e.g.,* trust companies) and non-community credit unions (*i.e.,* those institutions unable to serve the general public) from the computation. For the purposes of this analysis, a multiple common bond credit union already serving the area as an underserved area is considered able to serve the general public and thus would not be excluded. With both of these exclusions, NCUA will recalculate the concentration of facilities ratio to determine whether, as a result, the proposed area qualifies as ''underserved by other depository institutions.''

As one alternative to the concentration of facilities ratio, a proposed area will qualify as ''underserved by other depository institutions'' if it is designated an ''underserved county'' by NCUA based on data produced by the Consumer Financial Protection Bureau (available at: *http://www.consumerfinance.gov/guidance/#ruralunderserved).* NCUA will make its list of ''underserved counties'' available on its Web site.

As another alternative to the concentration of facilities ratio, a proposed area will qualify as ''underserved by other depository institutions'' if the credit seeking to serve it, using a metric of its own choosing, provided that it is based on NCUA or other Federal banking agency data, that establishes to NCUA that the proposed area is ''underserved by other depository institutions.''

III.C—NCUA Approval

If NCUA approves the request to add an ''underserved area,'' the credit union will be issued an amendment to Section 5 of its charter.

III.D—Approval to Serve an Already Approved ''Underserved Area''

Once a credit union is initially approved to serve an ''underserved area,'' other credit unions that subsequently apply may be approved to serve the same area. To be approved, the area must qualify as ''underserved'' at the time the new applicant applies. An applicant must demonstrate that the area continues to be ''distressed'', as provided above, only if a new decennial Census has been published since the date the area was last approved. In any case, the applicant must demonstrate that the area still has ''significant unmet needs'' for loans or credit union services (to qualify as an ''investment area''), and remains ''underserved by other depository institutions'' (to qualify as ''underserved'').

III.E—Business Plan

A federal credit union that desires to include an underserved community in its field of membership must first develop, and submit for approval, a business plan specifying how it will serve the community. In addition, the business plan must include a SUN section as provided in section III.B.2.b. above. The credit union will be expected to regularly review the business plan to determine if the community is being adequately served. The Office of Consumer Financial Protection and Access Director may require periodic service status reports from a credit union about the ''underserved area'' to ensure that the needs of the community are being met, and must require such reports before NCUA allows a multiple common bond federal credit union to add an additional ''underserved area.''

III.F—Service Facility

Once an ''underserved area'' has been added to a federal credit union's field of membership, the credit union must establish within two years, and maintain, an office or service facility in the community. A service facility is defined as a place where shares are accepted for members' accounts, loan applications are accepted and loans are disbursed. By definition, a service facility includes a credit union-owned branch, a shared branch, a mobile branch, or an office operated on a regularly scheduled weekly basis or a credit union owned electronic facility that meets, at a minimum, the above requirements. This definition does not include an ATM or the credit union's Internet Web site.

IV—Appeal Procedures for Denial of Underserved Area

IV.A—NCUA Disapproval

When NCUA disapproves any application to add an ''underserved area'' in whole or in part, under this chapter, the applicant will be informed in writing of the:

- Specific reasons for the action;
- Options to consider, if appropriate, for gaining approval; and
- Appeal procedures.

IV.B—Appeal of Office of Consumer Financial Protection and Access Director Decision

If the Office of Consumer Financial Protection and Access Director denies an ''underserved area'' request, the federal credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial. The appeal must be clearly identified as such and address the specific reason(s) the federal credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access. NCUA central office staff will make an independent review of the facts and present the appeal to the NCUA Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the Office of Consumer Financial Protection and Access Director for reconsideration. A reconsideration will contain new and material evidence addressing the reasons for the initial denial. The Office of Consumer Financial Protection and Access Director will have 30 days from the date of the receipt of the request for reconsideration to make a final decision. If the request is again denied, the applicant may proceed with the appeal process within 60 days of the date of the last denial. A second request for reconsideration will be treated as an appeal to the NCUA Board.

Chapter 4—Charter Conversions

I—Introduction

A charter conversion is a change in the jurisdictional authority under which a credit union operates.

Federal credit unions receive their charters from NCUA and are subject to its supervision, examination, and regulation.

State-chartered credit unions are incorporated in a particular state, receiving their charter from the state agency responsible for credit unions and subject to the state's regulator. If the state-chartered credit union's deposits are federally insured, it will also fall under NCUA's jurisdiction.

A federal credit union's power and authority are derived from the Federal Credit Union Act and NCUA Rules and Regulations. State-chartered credit unions are governed by state law and regulation. Certain federal laws and regulations also apply to federally insured state chartered credit unions.

There are two types of charter conversions: federal charter to state charter and state charter to federal charter. Common bond and community requirements are not an issue from NCUA's standpoint in the case of a federal to state charter conversion. The procedures and forms relevant to both types of charter conversion are included in appendix 4.

II—Conversion of a State Credit Union to a Federal Credit Union

II.A—General Requirements

Any state-chartered credit union may apply to convert to a federal credit union. In order to do so it must:

- Comply with state law regarding conversion and file proof of compliance with NCUA;
- File the required conversion application, proposed federal credit union organization certificate, and other documents with NCUA;
- Comply with the requirements of the Federal Credit Union Act, *e.g.,* chartering and reserve requirements; and
- Be granted federal share insurance by NCUA.

Conversions are treated the same as any initial application for a federal charter, including an on-site examination by NCUA where appropriate. NCUA will also consult with the appropriate state authority regarding the credit union's current financial condition, management expertise, and past performance. Since the applicant in a conversion is an ongoing credit union, the economic advisability of granting a charter is more readily determinable than in the case of an initial charter applicant.

A converting state credit union's field of membership must conform to NCUA's chartering policy. The field of membership will be phrased in accordance with NCUA chartering policy. However, if the converting credit union is a multiple group charter and the new federal charter is a multiple group, then the new federal charter may retain in its field of membership any group that the state credit union was serving at the time of conversion. Subsequent changes must conform to NCUA chartering policy in effect at that time.

If the converting credit union is a community charter and the new federal charter is community-based, it must meet the community field of membership requirements set forth in Chapter 2, Section V of this manual. If the state-chartered credit union's community boundary is more expansive than the approved federal boundary, only members of record outside of the new community boundary may continue to be served.

The converting credit union, regardless of charter type, may continue to serve members of record. The converting credit union may retain in its field of membership any group or community added pursuant to state emergency provisions.

II.B—Submission of Conversion Proposal to NCUA

The following documents must be submitted with the conversion proposal:

- Conversion of State Charter to Federal Charter (NCUA 4000);
- Organization Certificate (NCUA 4008). Only Part (3) and the signature/notary section should be completed and, where applicable, signed by the credit union officials.
- Report of Officials and Agreement to Serve (NCUA 4012);
- The Application to Convert From State Credit Union to Federal Credit Union (NCUA 4401);
- The Application and Agreements for Insurance of Accounts (NCUA 9500);
- Certification of Resolution (NCUA 9501);
- Written evidence regarding whether the state regulator is in agreement with the conversion proposal; and

• Business plan, as appropriate, including the most current financial report and delinquent loan schedule.

If the state charter is applying to become a federal community charter, it must also comply with the documentation requirements included in Chapter 2, Section V.A.2 of this manual.

II.C—NCUA Consideration of Application To Convert

II.C.1—Review by the Office of Consumer Financial Protection and Access Director

The application will be reviewed to determine that it is complete and that the proposal is in compliance with Section 125 of the Federal Credit Union Act. This review will include a determination that the state credit union's field of membership is in compliance with NCUA's chartering policies. The Office of Consumer Financial Protection and Access Director may make further investigation into the proposal and may require the submission of additional information to support the request to convert.

II.C.2—On-Site Review

NCUA may conduct an on-site examination of the books and records of the credit union. Non-federally insured credit unions will be assessed an insurance application fee.

II.C.3—Approval by the Office of Consumer Financial Protection and Access Director and Conditions to the Approval

The conversion will be approved by the Office of Consumer Financial Protection and Access Director if it is in compliance with Section 125 of the Federal Credit Union Act and meets the criteria for federal insurance. Where applicable, the Office of Consumer Financial Protection and Access Director will specify any special conditions that the credit union must meet in order to convert to a federal charter, including changes to the credit union's field of membership in order to conform to NCUA's chartering policies. Some of these conditions may be set forth in a Letter of Understanding and Agreement (LUA), which requires the signature of the officials and the appropriate NCUA regional director or Office of National Examinations and Supervision Director.

II.C.4—Notification

The Office of Consumer Financial Protection and Access Director will notify both the credit union and the state regulator of the decision on the conversion.

II.C.5—NCUA Disapproval

When NCUA disapproves any application to convert to a federal charter, the applicant will be informed in writing of the:

• Specific reasons for the action;

• Options to consider, if appropriate, for gaining approval; and

• Appeal procedures.

II.C.6—Appeal of Office of Consumer Financial Protection and Access Director Decision

If a conversion to a federal charter is denied by the Office of Consumer Financial Protection and Access Director, the applicant credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial. The appeal must be clearly identified as such and address the specific reason(s) the credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access. NCUA central office staff will make an independent review of the facts and present the appeal to the NCUA Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the Office of Consumer Financial Protection and Access Director for reconsideration. The request will not be considered as an appeal, but a request for reconsideration by the Office of Consumer Financial Protection and Access Director. The Office of Consumer Financial Protection and Access Director will have 30 business days from the date of the receipt of the request for reconsideration to make a final decision. If the application is again denied, the credit union may proceed with the appeal process to the NCUA Board within 60 days of the date of the last denial by the Office of Consumer Financial Protection and Access Director.

II.D—Action by Board of Directors

II.D.1—General

Upon being informed of the Office of Consumer Financial Protection and Access Director's preliminary approval, the board must:

• Comply with all requirements of the state regulator that will enable the credit union to convert to a federal charter and cease being a state credit union;

• Obtain a letter or official statement from the state regulator certifying that the credit union has met all of the state requirements and will cease to be a state credit union upon its receiving a federal charter. A copy of this document must be submitted to the Office of Consumer Financial Protection and Access Director;

• Obtain a letter from the private share insurer (includes excess share insurers), if applicable, certifying that the credit union has met all withdrawal requirements. A copy of this document must be submitted to the Office of Consumer Financial Protection and Access Director; and

• Submit a statement of the action taken to comply with any conditions imposed by the Office of Consumer Financial Protection and Access Director in the preliminary approval of the conversion proposal and, if applicable, submit the signed LUA.

II.D.Application for a Federal Charter

When the Office of Consumer Financial Protection and Access Director has received evidence that the board of directors has satisfactorily completed the actions described above, the federal charter and new Certificate of Insurance will be issued.

The credit union may then complete the conversion as discussed in the following section. A denial of a conversion application can be appealed. Refer to Section II.C.6 of this chapter.

II.E—Completion of the Conversion

II.E.—Effective Date of Conversion

The date on which the Office of Consumer Financial Protection and Access Director approves the Organization Certificate and the Application and Agreements for Insurance of Accounts is the date on which the credit union becomes a federal credit union. The Office of Consumer Financial Protection and Access Director will notify the credit union and the state regulator of the date of the conversion.

II.E.2—Assumption of Assets and Liabilities

As of the effective date of the conversion, the federal credit union will be the owner of all of the assets and will be responsible for all of the liabilities and share accounts of the state credit union.

II.E.3—Board of Directors' Meeting

Upon receipt of its federal charter, the board will hold its first meeting as a federal credit union. At this meeting, the board will transact such business as is necessary to complete the conversion as approved and to operate the credit union in accordance with the requirements of the Federal Credit Union Act and NCUA Rules and Regulations.

As of the commencement of operations, the accounting system, records, and forms must conform to the standards established by NCUA.

II.E.4—Credit Union's Name

Changing of the credit union's name on all signage, records, accounts, investments, and other documents should be accomplished as soon as possible after conversion. The credit union has 180 days from the effective date of the conversion to change its signage and promotional material. This requires the credit union to discontinue using any remaining stock of ''state credit union'' stationery immediately, and discontinue using credit cards, ATM cards, etc., within 180 days after the effective date of the conversion, or the reissue date whichever is later. The Office of Consumer Financial Protection and Access Director has the discretion to extend the timeframe for an additional 180 days. Member share drafts with the state-chartered name can be used by the members until depleted.

II.E.Reports to NCUA

Within 10 business days after commencement of operations, the recently converted federal credit union must submit to the Office of Consumer Financial Protection and Access Director the following:

• Report of Officials (NCUA 4501); and

• Financial and Statistical Reports, as of the commencement of business of the federal credit union.

III—Conversion of a Federal Credit Union to a State Credit Union

III.A—General Requirements

Any federal credit union may apply to convert to a state credit union. In order to do so, it must:

• Notify NCUA prior to commencing the process to convert to a state charter and state the reason(s) for the conversion;

• Comply with the requirements of Section 125 of the Federal Credit Union Act that

enable it to convert to a state credit union and to cease being a federal credit union; and

• Comply with applicable state law and the requirements of the state regulator.

It is important that the credit union provide an accurate disclosure of the reasons for the conversion. These reasons should be stated in specific terms, not as generalities. The federal credit union converting to a state charter remains responsible for the entire operating fee for the year in which it converts.

III.B—Special Provisions Regarding Federal Share Insurance

If the federal credit union intends to continue federal share insurance after the conversion to a state credit union, it must submit an Application for Insurance of Accounts (NCUA 9600) to the Office of Consumer Financial Protection and Access Director at the time it requests approval of the conversion proposal. The Office of Consumer Financial Protection and Access Director has the authority to approve or disapprove the application.

If the converting federal credit union does not intend to continue federal share insurance or if its application for continued insurance is denied, insurance will cease in accordance with the provisions of Section 206 of the Federal Credit Union Act.

If, upon its conversion to a state credit union, the federal credit union will be terminating its federal share insurance or converting from federal to non-federal share insurance, it must comply with the membership notice and voting procedures set forth in Section 206 of the Federal Credit Union Act and part 708 of NCUA's Rules and Regulations, and address the criteria set forth in Section 205(c) of the Federal Credit Union Act.

Where the state credit union will be non-federally insured, federal insurance ceases on the effective date of the charter conversion. If it will be otherwise uninsured, then federal insurance will cease one year after the date of conversion subject to the restrictions in Section 206(d)(1) of the Federal Credit Union Act. In either case, the state credit union will be entitled to a refund of the federal credit union's NCUSIF capitalization deposit after the final date on which any of its shares are federally insured.

The NCUA Board reserves the right to delay the refund of the capitalization deposit for up to one year if it determines that payment would jeopardize the NCUSIF.

III.C—Submission of Conversion Proposal to NCUA

Upon approval of a proposition for conversion by a majority vote of the board of directors at a meeting held in accordance with the federal credit union's bylaws, the conversion proposal will be submitted to the Office of Consumer Financial Protection and Access Director and will include:

• A current financial report;

• A current delinquent loan schedule;

• An explanation and appropriate documents relative to any changes in insurance of member accounts;

• A resolution of the board of directors;

• A proposed Notice of Special Meeting of the Members (NCUA 4221);

• A copy of the ballot to be sent to all members (NCUA 4506);

• If the credit union intends to continue with federal share insurance, an application for insurance of accounts (NCUA 9600);

• Evidence that the state regulator is in agreement with the conversion proposal; and

• A statement of reasons supporting the request to convert.

III.D—Approval of Proposal to Convert

III.D.1—Review by the Office of Consumer Financial Protection and Access Director

The proposal will be reviewed to determine that it is complete and is in compliance with Section 125 of the Federal Credit Union Act. The Office of Consumer Financial Protection and Access Director may make further investigation into the proposal and require the submission of additional information to support the request.

III.D.2—Conditions to the Approval

The Office of Consumer Financial Protection and Access Director will specify any special conditions that the credit union must meet in order to proceed with the conversion.

III.D.3—Approval by the Office of Consumer Financial Protection and Access Director

The proposal will be approved by the Office of Consumer Financial Protection and Access Director if it is in compliance with Section 125 and, in the case where the state credit union will no longer be federally insured, the notice and voting requirements of Section 206 of the Federal Credit Union Act.

III.D.4—Notification

The Office of Consumer Financial Protection and Access Director will notify both the credit union and the state regulator of the decision on the proposal.

III.D.UA Disapproval

When NCUA disapproves any application to convert to a state charter, the applicant will be informed in writing of the:

• Specific reasons for the action;

• If appropriate, options or suggestions that could be considered for gaining approval; and

• Appeal procedures.

III.D.6—Appeal of Office of Consumer Financial Protection and Access Director Decision

If the Office of Consumer Financial Protection and Access Director denies a conversion to a state charter, the federal credit union may appeal the decision to the NCUA Board. An appeal must be sent to the NCUA Board Secretary within 60 days of the date of denial. The appeal must be clearly identified as such and address the specific reason(s) the federal credit union disagrees with the denial. A copy of the appeal must be sent to the Office of Consumer Financial Protection and Access. NCUA central office staff will make an independent review of the facts and present the appeal to the NCUA Board with a recommendation.

Before appealing, the credit union may, within 30 days of the denial, provide supplemental information to the Office of Consumer Financial Protection and Access Director for reconsideration. The request will not be considered as an appeal, but a request for reconsideration by the Office of Consumer Financial Protection and Access Director. The Office of Consumer Financial Protection and Access Director will have 30 business days from the date of the receipt of the request for reconsideration to make a final decision. If the application is again denied, the credit union may proceed with the appeal process to the NCUA Board within 60 days of the date of the last denial by the Office of Consumer Financial Protection and Access Director.

III.E—Approval of Proposal by Members

The members may not vote on the proposal until it is approved by the Office of Consumer Financial Protection and Access Director. Once approval of the proposal is received, the following actions will be taken by the board of directors:

• The proposal must be submitted to the members for approval and a date set for a meeting to vote on the proposal. The proposal may be acted on at the annual meeting or at a special meeting for that purpose. The members must also be given the opportunity to vote by written ballot to be filed by the date set for the meeting.

• Members must be given advance notice (NCUA 4221) of the meeting at which the proposal is to be submitted. The notice must:

• Specify the purpose, time and place of the meeting;

• Include a brief, complete, and accurate statement of the reasons for and against the proposed conversion, including any effects it could have upon share holdings, insurance of member accounts, and the policies and practices of the credit union;

• Specify the costs of the conversion, *i.e.,* changing the credit union's name, examination and operating fees, attorney and consulting fees, tax liability, etc.;

• Inform the members that they have the right to vote on the proposal at the meeting, or by written ballot to be filed not later than the date and time announced for the annual meeting, or at the special meeting called for that purpose;

• Be accompanied by a Federal to State Conversion—Ballot for Conversion Proposal (NCUA 4506); and

• State in **bold** face type that the issue will be decided by a majority of members who vote.

• The proposed conversion must be approved by a majority of all of the members who vote on the proposal, a quorum being present, in order for the credit union to proceed further with the proposition, provided federal insurance is maintained. If the proposed state-chartered credit union will not be federally insured, 20 percent of the total membership must participate in the voting, and of those, a majority must vote in favor of the proposal. Ballots cast by members who did not attend the meeting but who submitted their ballots in accordance with instructions above will be counted with votes cast at the meeting. In order to have a suitable record of the vote, the voting at the meeting should be by written ballot as well.

• The board of directors shall, within 10 days, certify the results of the membership

vote to the Office of Consumer Financial Protection and Access Director. The statement shall be verified by affidavits of the Chief Executive Officer and the Recording Officer on NCUA 4505.

III.F—Compliance With State Laws

If the proposal for conversion is approved by a majority of all members who voted, the board of directors will:

• Ensure that all requirements of state law and the state regulator have been accommodated;

• Ensure that the state charter or the license has been received within 90 days from the date the members approved the proposal to convert; and

• Ensure that the Office of Consumer Financial Protection and Access Director is kept informed as to progress toward conversion and of any material delay or of substantial difficulties which may be encountered.

If the conversion cannot be completed within the 90-day period, the Office of Consumer Financial Protection and Access Director should be informed of the reasons for the delay. The Office of Consumer Financial Protection and Access Director may set a new date for the conversion to be completed.

III.G—Completion of Conversion

In order for the conversion to be completed, the following steps are necessary:

• The board of directors will submit a copy of the state charter to the Office of Consumer Financial Protection and Access Director within 10 days of its receipt. This will be accompanied by the federal charter and the federal insurance certificate. A copy of the financial reports as of the preceding month-end should be submitted at this time.

• The Office of Consumer Financial Protection and Access Director will notify the credit union and the state regulator in writing of the receipt of evidence that the credit union has been authorized to operate as a state credit union.

• The credit union shall cease to be a federal credit union as of the effective date of the state charter.

• If the Office of Consumer Financial Protection and Access Director finds a material deviation from the provisions that would invalidate any steps taken in the conversion, the credit union and the state regulator shall be promptly notified in writing. This notice may be either before or after the copy of the state charter is filed with the Office of Consumer Financial Protection and Access Director. The notice will inform the credit union as to the nature of the adverse findings. The conversion will not be effective and completed until the improper actions and steps have been corrected.

• Upon ceasing to be a federal credit union, the credit union shall no longer be subject to any of the provisions of the Federal Credit Union Act, except as may apply if federal share insurance coverage is continued. The successor state credit union shall be immediately vested with all of the assets and shall continue to be responsible for all of the obligations of the federal credit union to the same extent as though the conversion had not taken place. Operation of the credit union from this point will be in accordance with the requirements of state law and the state regulator.

• If the Office of Consumer Financial Protection and Access Director is satisfied that the conversion has been accomplished in accordance with the approved proposal, the federal charter will be canceled.

• There is no federal requirement for closing the records of the federal credit union at the time of conversion or for the manner in which the records shall be maintained thereafter. The converting credit union is advised to contact the state regulator for applicable state requirements.

• The credit union shall neither use the words ''Federal Credit Union'' in its name nor represent itself in any manner as being a federal credit union.

• Changing of the credit union's name on all signage, records, accounts, investments, and other documents should be accomplished as soon as possible after conversion. Unless it violates state law, the credit union has 180 days from the effective date of the conversion to change its signage and promotional material. This requires the credit union to discontinue using any remaining stock of ''federal credit union'' stationery immediately, and discontinue using credit cards, ATM cards, etc., within 180 days after the effective date of the conversion, or the reissue date, whichever is later. The Office of Consumer Financial Protection and Access Director has the discretion to extend the timeframe for an additional 180 days. Member share drafts with the federal chartered name can be used by the members until depleted. If the state credit union is not federally insured, it must change its name and must immediately cease using any credit union documents referencing federal insurance.

• If the state credit union is to be federally insured, the Office of Consumer Financial Protection and Access Director will issue a new insurance certificate.

APPENDIX 1 GLOSSARY

These definitions apply only for use with this Manual. Definitions are not intended to be all inclusive or comprehensive. This Manual, the Federal Credit Union Act, and NCUA Rules and Regulations, as well as state laws, may be used for further reference.

Adequately capitalized—A credit union is considered ''adequately capitalized'' when it meets the ''adequately capitalized'' definition in Part 702 of NCUA's Rules and Regulations. A multiple common bond credit union must be ''adequately capitalized'' in order to add new groups to its charter. The Office of Consumer Financial Protection and Access director, with input from the appropriate regional director or Office of National Examinations and Supervision Director, may determine that a less than ''adequately capitalized'' credit union can qualify for an expansion if it is making reasonable progress toward becoming ''adequately capitalized,'' and the addition of the group would not adversely affect the credit union's capitalization level.

Affinity—A relationship upon which a community charter is based. Acceptable affinities include living, working, worshiping, or attending school in a community.

Appeal—The right of a credit union or charter applicant to request a formal review of the Office of Consumer Financial Protection and Access, regional director's or Office of National Examinations and Supervision Director's adverse decision by the National Credit Union Administration Board.

Associational common bond—A common bond comprised of members and employees of a recognized association. It includes individuals (natural persons) and/or groups (non-natural persons) whose members participate in activities developing common loyalties, mutual benefits, and mutual interests.

Business plan—Plan submitted by a charter applicant or existing federal credit union addressing the economic advisability of a proposed charter or field of membership addition.

Charter—The document which authorizes a group to operate as a credit union and defines the fundamental limits of its operating authority, generally including the persons the credit union is permitted to accept for membership. Charters are issued by the National Credit Union Administration for federal credit unions and by the designated state chartering authority for credit unions organized under the laws of that state.

Common bond—The characteristic or combination of characteristics which distinguishes a particular group of persons from the general public. There are two common bonds which can serve as a basis for a group forming a federal credit union or being included in an existing federal credit union's field of membership: Occupational—employment by the same company, related companies or in a trade, industry, or profession (TIP); and associational—membership in the same association.

Community credit union—A credit union whose field of membership consists of persons who live, work, worship, or attend school in the same well-defined local community, neighborhood, or rural district.

Credit union—A member-owned, not-for-profit cooperative financial institution formed to permit those in the field of membership specified in the charter to save, borrow, and obtain related financial services.

Economic advisability—An overall evaluation of the credit union's or charter applicant's ability to operate successfully.

Emergency merger—Pursuant to Section 205(h) of the Federal Credit Union Act, authority of NCUA to merge two credit unions without regard to common bond policy.

Exclusionary clause—A limitation, written in a credit union's charter, which precludes the credit union from serving a portion of a group which otherwise could be included in its field of membership.

Federal share insurance—Insurance coverage provided by the National Credit Union Share Insurance Fund and administered by the National Credit Union Administration. Coverage is provided for qualified accounts in all federal credit unions and participating state credit unions.

Field of membership—The persons (including organizations and other legal entities) a credit union is permitted to accept for membership.

Household—Persons living in the same residence maintaining a single economic unit.

Housekeeping Amendment—A field of membership amendment to delete groups, change group names, change group locations, remove exclusionary clauses, and to add other persons eligible for credit union membership by virtue of their close relationship to a common bond group or the community for community charters.

Immediate family member—A spouse, child, sibling, parent, grandparent, or grandchild. This includes stepparents, stepchildren, stepsiblings, and adoptive relationships.

In danger of insolvency—In making the determination that a particular credit union is in danger of insolvency, NCUA will establish that the credit union falls into one or more of the following categories:

1. The credit union's net worth is declining at a rate that will render it insolvent within 24 months. In projecting future net worth, NCUA may rely on data in addition to Call Report data. The trend must be supported by at least 12 months of historic data.

2. The credit union's net worth is declining at a rate that will take it under two percent (2%) net worth within 12 months. In projecting future net worth, NCUA may rely on data in addition to Call Report data. The trend must be supported by at least 12 months of historic data.

3. The credit union's net worth, as self-reported on its Call Report, is significantly undercapitalized, and NCUA determines that there is no reasonable prospect of the credit union becoming adequately capitalized in the succeeding 36 months. In making its determination on the prospect of achieving adequate capitalization, NCUA will assume that, if adverse economic conditions are affecting the value of the credit union's assets and liabilities, including property values and loan delinquencies related to unemployment, these adverse conditions will not further deteriorate.

Letter of Understanding and Agreement—Agreement between NCUA and federal credit union officials not to engage in certain activities and/or to establish reasonable operational goals. These are normally entered into with new charter applicants for a limited time.

Mentor—An individual who provides guidance and assistance to newly chartered, small, or low-income credit unions. All new federal credit unions are encouraged to establish a mentor relationship with a trained, experienced credit union individual or an existing credit union.

Metropolitan Statistical Area—The Office of Management and Budget defines a metropolitan statistical area as an urbanized area that has at least one urbanized area in excess of 50,000 and ''comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting.''

Merger—Absorption by one credit union of all of the assets, liabilities and equity of another credit union. Mergers must be approved by the National Credit Union Administration and by the appropriate state regulator whenever a state credit union is involved.

Multiple common bond credit union—A credit union whose field of membership consists of more than one group, each of which has a common bond of occupation or association.

Occupational common bond—Employment by the same entity or related entities or a Trade, Industry, or Profession.

Once a member, always a member—A provision of the Federal Credit Union Act which permits an individual to remain a member of the credit union until he or she chooses to withdraw or is expelled from the membership of the credit union. Under this provision, leaving a group that is named in the credit union's charter does not terminate an individual's membership in the credit union.

Organizations of such persons—An organization or organizations composed exclusively of persons who are within the field of membership of the credit union.

Overlap—The situation which results when a group is eligible for membership in more than one credit union.

Primary potential members—Members or employees who belong to an associational or occupational group.

Purchase and assumption—Purchase of all or part of the assets of and assumption of all or part of the liabilities of one credit union by another credit union. The purchased and assumed credit union must first be placed into involuntary liquidation.

Service area—The area that can reasonably be served by the service facilities accessible to the groups within the field of membership.

Service facility—A place where shares are accepted for members' accounts, loan applications are accepted or loans are disbursed. This definition includes a credit union owned branch, a mobile branch, an office operated on a regularly scheduled weekly basis, a credit union owned ATM, a video teller machine or a credit union owned electronic facility that meets, at a minimum, these requirements. A service facility also includes a shared branch or a shared branch network if either: (1) the credit union has an ownership interest in the service facility either directly or through a CUSO or similar organization; or (2) the service facility is local to the credit union and the credit union is an authorized participant in the service center. This definition does not include the credit union's Internet Web site. A service facility does not include an ATM or interest in a shared branch network for purposes of serving an underserved area.

Single associational common bond credit union—A credit union whose field of membership includes members and employees of a recognized association.

Single common bond credit union—A credit union whose field of membership consists of one group which has a common bond of occupation or association.

Single occupational common bond credit union—A credit union whose field of membership consists of employees of the same entity or related entities or part of a Trade, Industry, or Profession (TIP).

Spin-off—The transfer of a portion of the field of membership, assets, liabilities, shares, and capital of one credit union to a new or existing credit union.

Subscribers—For a federal credit union, at least seven individuals who sign the charter application and pledge at least one share.

Trade, Industry, or Profession (TIP)—A single occupational common bond credit union based on employment in a trade, industry, or profession including employment at any number of corporations or other legal entities that while not under common ownership—have a common bond by virtue of producing similar products, providing similar services, or participating in the same type of business.

Underserved community—A local community, neighborhood, or rural district that is an ''investment area'' as defined in Section 103(16) of the Community Development Banking and Financial Institutions Act of 1994. The area must also be underserved based on other NCUA and federal banking agency data.

Unsafe or unsound practice—Any action, or lack of action, which would result in an abnormal risk or loss to the credit union, its members, or the National Credit Union Share Insurance Fund.

BILLING CODE 7535–01–P

APPENDIX 2

LETTER OF UNDERSTANDING AND AGREEMENT

To the Board of Directors and Other Officials
_____Federal Credit Union

Since the purposes of credit unions are to promote thrift and to make funds available for loans to credit union members for provident and productive purposes, and since newly chartered credit unions do not generally have sufficient reserves to cover large losses on loans or meet unduly large liquidity requirements, Federal insurance coverage of member accounts under the National Credit Union Share Insurance Fund will be granted to the above named credit union subject to the conditions listed in this Letter of Understanding and Agreement and in the Organization Certificate and Application and Agreements for Insurance of Accounts. These terms are listed below and are subject to acceptance by authorized credit union officials.

1. The credit union will refrain from soliciting or accepting brokered fund deposits from any source without the prior written approval of the Regional Director.

2. The credit union will refrain from the making of large loans, that is, loans in excess of 5 percent of unimpaired capital and surplus, to any one member or group of members without the prior written approval of the Regional Director.

3. The credit union will not establish or invest in a Credit Union Service Organization (CUSO) without the prior written approval of the Regional Director.

4. The credit union will not enter into any insurance programs whereby the credit union member finances the payment of insurance premiums through loans from the credit union.

5. Any special insurance plan/program, that is, insurance other than usual and normal surety bonding or casualty or liability or loan protection and life savings insurance coverage, which the credit union officials intend to undertake, will be submitted to the Regional Director of the National Credit Union Administration for written approval prior to the officials committing the credit union thereto.

6. The credit union will prepare and mail to the district examiner financial and statistical reports as required by the Federal Credit Union Act and Bylaws by the 20th of each month following that for which the report is prepared.

7. As the credit union's officials gain experience and the credit union achieves target levels of growth and profitability, the above terms and conditions may be renegotiated by the two parties.

We, the undersigned officials of the_____Federal Credit Union, as authorized by the board of directors, acknowledge receipt of and agree to the attached Letter of Understanding and Agreement dated_____.

This Letter of Understanding and Agreement has been voluntarily entered into with the National Credit Union Administration. We agree to comply with all terms and conditions expressed in this Letter of Understanding and Agreement.

Should the NCUA Board determine that these terms and conditions have not been complied with or that the board of directors or other officials have not conducted the affairs of the credit

union in a sound and prudent manner, the NCUA Board may terminate insurance coverage of the credit union. If actions by the officials, in violation of this Letter of Understanding and Agreement, cause the credit union to become insolvent, the officials assume such personal liability as may result from their actions.

The term of this Letter of Understanding and Agreement shall be for the period of at least 24 months from the date the credit union is insured. This Letter of Understanding and Agreement may, at the option of the Regional Director, be extended for an additional 24 months at the end of the initial term of this agreement.

Dated this_____of_____.
(day) (month) (year)

NATIONAL CREDIT UNION ADMINISTRATION BOARD
ON BEHALF OF THE NATIONAL CREDIT UNION SHARE INSURANCE FUND

_____
Office of Consumer Financial Protection and Access
Director

_____Federal Credit Union

By:

_____
Chief Executive Officer Date

_____
Chief Financial Officer Date

_____
Secretary Date

APPENDIX 3

NCUA OFFICES

OFFICE OF CONSUMER FINANCIAL PROTECTION AND ACCESS
1775 Duke Street
Alexandria, VA 22314-3428

Phone: 703-518-1150
Fax: 703-518-6672
EMAIL: dcamail@ncua.gov

Within the Office of Consumer Financial Protection and Access, the Division of Consumer Access and Division of Consumer Access – South share the responsibility for chartering and field-of-membership matters, low-income designations, charter conversions and bylaw amendments.

REGION 1 – ALBANY
9 Washington Square
Washington Avenue Extension
Albany, NY 12205

Phone: 518-862-7400
Fax: 518-862-7420
EMAIL: Region1@ncua.gov

Region 1 is responsible for all federally insured credit unions in Connecticut, Maine, Massachusetts, Michigan, New Hampshire, New York, Rhode Island, Vermont, and Wisconsin.

REGION 2 – CAPITAL
1900 Duke Street, Suite 300
Alexandria, VA 22314

Phone: 703-519-4600
Fax: 703-519-4620
EMAIL: Region2@ncua.gov

Region 2 is headquartered in Alexandria, Virginia, and encompasses the states of Delaware, Maryland, New Jersey, Ohio, Pennsylvania, Virginia and West Virginia, and the District of Columbia.

REGION 3 – ATLANTA
7000 Central Parkway, Suite 1600
Atlanta, GA 30328-4598

Phone: 678-443-3000
Fax: 678-443-3020
EMAIL: Region3@ncua.gov

States in Region 3 include Alabama, Arkansas, Florida, Georgia, Indiana, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina and Tennessee, as well as Puerto Rico and the U.S. Virgin Islands.

REGION 4 – AUSTIN
4807 Spicewood Springs Rd.
Suite 5200
Austin, TX 78759-8490

Phone: 512-342-5600
Fax: 512-342-5620
EMAIL: Region4@ncua.gov

Region 4, headquartered in Austin Texas, covers Colorado, Illinois, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming.

REGION 5 – TEMPE
1230 W. Washington Street
Suite 301
Tempe, AZ 85281

Phone: 602-302-6000
Fax: 602-302-6024
EMAIL: Region5@ncua.gov

Region 5 headquartered in Tempe, Arizona, covers Alaska, Arizona, California, Guam, Hawaii, Idaho, Nevada, Oregon, Utah, and Washington.

APPENDIX 4

NCUA FORMS

Form Number	Form Title
NCUA 4000	Conversion of State Charter to a Federal Charter – Federal Credit Union Investigation Report
NCUA 4001	Federal Credit Union Investigation Report
NCUA 4008	Organization Certificate
NCUA 4009	Approval of Organization Certificate and Certification of Insurance
NCUA 4012	Report of Official and Agreement to Serve
NCUA 4015	Application for Field of Membership Amendment (use for all multiple common bond expansions involving groups of 5,000 or more persons)
NCUA 4015-A	Application for Field of Membership Amendment (use for all multiple common bond expansions involving groups of 3,000 to 4,999 persons)
NCUA 4015-EZ	Application for Field of Membership Amendment (use for all single common bond expansions and multiple common bond expansions involving groups of less than 3,000 persons)
NCUA 4221	Notice of Meeting of Members to Convert from a Federal to State Chartered Credit Union
NCUA 4401	Application to Convert from a State to a Federal Credit Union
NCUA 4505	Affidavit - Proof of Results of Membership Vote - Proposed Conversion From Federal Credit Union to State Credit Union
NCUA 4506	Federal to State Conversion - Ballot for Conversion Proposal
NCUA 9500	Application and Agreements for Insurance of Accounts
NCUA 9501	Certification of Resolutions
NCUA 9600	Information to be Provided in Support of the Application of a State Chartered Credit Union for Insurance of Accounts

CONVERSION OF STATE CHARTER TO FEDERAL CHARTER

FEDERAL CREDIT UNION INVESTIGATION REPORT

This report must be filled in completely and submitted with the other completed forms listed in Chapter 4 and in the instructions for this form.

A. INFORMATION FOR CHARTER AND BYLAWS

1. Proposed Name:_____Federal Credit Union
Second Choice of Name:_____Federal Credit Union

2. Contact Person_____
Bus. Tel. No./Area Code:_____Res. Tel. No./Area Code_____

3. The credit union will maintain its office at:

_____	_____	_____	_____
(City)	(County)	(State)	(Zip)

4. Permanent mailing address of credit union:

_____
_____
_____

5. Define proposed field of membership (Attach a copy of current state charter field of membership):

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

6. The board will have (an odd number 5 to 15)_____members; the credit committee (an odd number, 3 to 7)_____members; the supervisory committee (3 to 5)_____members. Each official must complete a Report of Official and Agreement to Serve (NCUA 4012) which is to be submitted with this investigation report.
1.

B. CHARACTER AND FITNESS OF SUBSCRIBERS

7. Type or print the list of the subscribers who have signed the organization certificate (7 not more than 10 persons). Names should be IDENTICAL to signatures on the Organization Certificate (NCUA 4008). Each subscriber listed below has subscribed to at least one share in accordance with Section 103 of the Federal Credit Union Act:

***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**
***Name*:**	***Address*:**	
***Occupation*:**		***Years of Membership*:**

ANY ADDITIONAL COMMENTS OR INFORMATION THAT IS DEEMED PERTINENT OR HELPFUL IN GIVING CONSIDERATION TO THIS APPLICATION SHOULD BE INCLUDED AS AN ATTACHMENT.

The undersigned certifies that to the best of his/her knowledge and belief the above information is true and correct.

I do (do not) recommend that a charter be granted to this group.
Signature_____, Organizer
Organizer's Address: _____
_____
_____

FORM 4000 INSTRUCTIONS

A. INFORMATION FOR CHARTERS AND BYLAWS

The subscriber should select a name for the proposed credit union. It is the responsibility of the federal credit union organizers to ensure that the proposed federal credit union name does not constitute an infringement on the name of any corporation in its trade area. The last three words in the name must be "Federal Credit Union." Since the name selected should not duplicate exactly the name of an existing credit union, item 1 provides space for a second choice.

The territory of operations of a Federal credit union is described in the field of membership, item 5. The principal office of the credit union will usually be maintained at a location described in the field of membership.

The proposed field of membership should be defined so clearly that it leaves no room for any doubt as to whom the credit union is to serve or the area which it is to operate. Corporations and other organizations referred to in the definition of the field of membership should be designated by the exact names rather than by some local or popular contraction of these names. Any segment of a larger organization should be identified with the parent. The field of membership for each type of common bond and samples are discussed in detail in Chapter 2 of the "*Chartering and Field of Membership Manual*."

With the guidance of the organizer, the subscribers to the Organization Certificate decide on the number of directors and credit committee members. The board and credit committee must be composed of an odd number of members. The supervisory committee is appointed by the board of directors.

B. CHARACTER AND FITNESS OF SUBSCRIBERS

The names and address of the subscribers should be recorded legibly and completely in item 7 of this report. It is from this information that the National Credit Union Administration prepares Section 3 of the charter. The names of the subscribers must be IDENTICAL to their signatures on the Organization Certificate.

C. SUBMITTAL OF CHARTER APPLICATION

In addition to this Investigation Report, the following should be submitted to the Director of NCUA's Office of Consumer Financial Protection and Access:

1. Application to Convert, NCUA 4401 – one original;

2. Written evidence regarding whether the state regulator is in agreement with the conversion proposal;

3. Application and Agreements for Insurance of Accounts, NCUA 9500 - one original;

4. Certificate of Resolution, NCUA 9501 - one original;

5. Organization Certificate, NCUA 4008 - one notarized original. At least seven, *but no more than ten persons*, must sign the organization certificate. The person administering the oath must not be one of the subscribers. The oath on the organization certificate must be executed and show the notary's seal and date the commission expires as required by State law;

6. Report of Official and Agreement to Serve, NCUA 4012 – one original for each board member, credit committee member, and supervisory committee member;

7. Most current financial report and delinquent loan schedule; and

8. Business Plan - refer to Chapter 1 of the *Chartering and Field of Membership Manual* for a discussion of the components of an acceptable business plan.

~~1.~~

FEDERAL CREDIT UNION INVESTIGATION REPORT

This form must be filled in completely and submitted with the other completed forms listed in the instructions to this form.

A. INFORMATION FOR CHARTER AND BYLAWS

1. Proposed name:_____Federal Credit Union
   Second choice:_____Federal Credit Union

2. Contact Person: _____
   Business Tel.: _____
   Residence Tel.: _____
   Address: _____
   _____
   _____

3. The credit union will maintain its offices at:

   _____
   (City, State, County, Zip Code)

3a. Proposed permanent mailing address of credit union:

   _____
   _____
   _____

4. Define proposed field of membership: _____
_____
_____
_____
_____
_____
_____
_____
_____

5. The board will have (an odd number, 5 to 15)_____members; the credit committee will have (an odd number, 3 to 7)_____members; the supervisory committee will have (3 to 5)_____members. Each official must complete a Report of Official and Agreement to Serve (NCUA 4012) which is to be submitted with this investigation report.

B. ECONOMIC ADVISABILITY OF ORGANIZING PROPOSED CREDIT UNION

(Attach a separate sheet if space available is not adequate.)

GENERAL INFORMATION

1. **Potential membership: _____**

   NOTE: Number of employees for occupational, active members for associational (or families for religious groups), or population per most recent census for community-type fields of membership.

2. **Potential interest (survey results).**

   NOTE: Sample must consist of a minimum of 250 potential members. Copy of survey form(s) utilized should be attached.

   Number of people surveyed: _____
   Number of people responding to survey: _____
   Number of people pledging an initial deposit: _____
   Total dollars pledged: $_____
   Number pledging systematic savings: __ Total dollars pledged (per month): $_____

3. **Number of persons attending the charter-organization meeting: _____**

4. **Attach a business plan containing, at a minimum, the following elements:**

   - **mission statement;**
   - **analysis of market conditions, including if applicable, geographic, demographic, employment, income, housing, and other economic data;**
   - **evidence of member support;**
   - **goals for shares, loans, and for number of members;**
   - **financial services needed/desired;**
   - **financial services to be provided to members of all segments within the field of membership;**
   - **how/when services are to be implemented;**
   - **organizational/management plan addressing qualification and planned training of officials/employees;**
   -

- **continuity plan for directors, committee members, and management staff;**
- **operating facilities, to include office space/equipment and supplies, safeguarding of assets, insurance coverage, etc.;**
- **type of record keeping and data processing system;**
- **detailed semiannual pro forma financial statements (balance sheet, income and expense projections) for 1st and 2nd year, including assumptions - e.g., loan and dividend rates;**
- **plans for operating independently;**
- **written policies (shares, lending, investments, funds management, capital accumulation, dividends, collections, etc.);**
- **source of funds to pay expenses during initial months of operation, including any subsidies, assistance, etc., and terms or conditions of such resources; and**
- **evidence of sponsor commitment (or other source of support) if subsidies are critical to success of the federal credit union. Evidence may be in the form of letters, contracts, financial statements from the sponsor, and any other such document on which the proposed federal credit union can substantiate its projections.**

5. What potential difficulties do you detect in the elected officials carrying out their management responsibilities or in the FCU achieving its stated objectives?

_____
_____
_____
_____

6. What provisions have been made to overcome potential difficulties?

_____
_____
_____
_____

Dates of planned contacts by organizer to determine progress and to assist the group:

First Contact Date: _____
Second Contact Date: _____
Third Contact Date: _____

SPECIFIC INFORMATION - OCCUPATIONAL (same company) CHARTER APPLICANTS

1. How long has the sponsor company been in existence? _____

2. What was the highest number of employees during the past three years? _____Lowest number during the past three years?_____If a large variance,

please explain. _____

3. Are there any contemplated changes in the corporate structure of the company? ___If yes, explain. _____

4. Have there been any significant changes in the corporate structure in the past three years?_____If yes, please explain. _____

5. Are there any negotiations now in progress between management and labor that could lead to work stoppages?_____If yes, please explain. _____

6. If the credit union cannot operate on the employer's property, explain how the credit union will be able to transact business effectively with the members.

_____

7. If the employees to be served by the credit union work in more than one location or city, identify each location with the corresponding number of employees working at each. _____

_____

_____

_____

_____

8. Are there other employees of the company who are not being included in the proposed field of membership?_____If so, give the number and location of the other employees and explain why they are not included in the proposed credit union's field of membership. _____

_____

_____

_____

_____

SPECIFIC INFORMATION - OCCUPATIONAL (trade, industry or profession) CHARTER APPLICANTS

1. Explain how the credit union will be able to transact business effectively with the members. _____

_____

_____

_____

_____

_____

_____

_____

_____

SPECIFIC INFORMATION - ASSOCIATIONAL CHARTER APPLICANTS

1. State the purpose and goals of the organization sponsoring this charter.

_____
_____
_____
_____
_____
_____
_____
_____

2. List the types of activities and their frequency, which the organization sponsors that provide contact among the members and from which common loyalties, mutual benefits, and mutual interests are developed. _____

_____
_____
_____
_____
_____
_____
_____
_____

3. In what year was the organization established?_____Is it incorporated? _____
Where is the headquarters located? _____

4. Give statistics as to trends in membership during the last five years. _____

_____
_____
_____
_____

5. What is the frequency of membership meetings? _____
Average attendance:_____Dues required: $_____

6. State the geographic territory where members reside. _____

_____
_____
_____
_____

7. Submit a copy of the current bylaws of the association, the constitution, articles of incorporation, or equivalent documentation and recent financial statements, i.e. balance sheet, and income and expense statement, with this application.

8. If the bylaws, constitution, articles of incorporation, or equivalent documentation provide for more than one type of membership and if all classes of membership are to be included in the credit union's field of membership, provide justification for the inclusion of other than "regular" members.

_____

_____

_____

_____

_____

SPECIFIC INFORMATION – MULTIPLE COMMON BOND CHARTER APPLICANTS

1. Explain how the credit union will be able to transact business effectively with the members. _____

_____

_____

_____

_____

_____

_____

_____

SPECIFIC INFORMATION - COMMUNITY CHARTER APPLICANTS

1. Community charters must be based on a well-defined local community, neighborhood, or rural district where individuals have common interests and/or interact. Please refer to Chapter 2, Section V of the *"Chartering and Field of Membership Manual"* when answering this question.

2. Provide a map which clearly outlines the credit union's proposed community boundaries and identify proposed service facilities.
1.

C. CHARACTER AND FITNESS OF SUBSCRIBERS

1. List of subscribers who have signed the Organization Certificate (7 not more than 10 persons). Names should be IDENTICAL to signature on the Organization Certificate (NCUA 4008). Each subscriber listed below has subscribed to at least one share in accordance with Section 103 of the Federal Credit Union Act:

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

Name: _____
Address: _____
_____
Occupation: _____
Years of Residence: _____

2. Are all of the subscribers within the field of membership?_____Do they

appear to be representative of the group described in the definition of the field of membership?_____If not, explain. _____
_____
_____
_____
_____

3. Does your investigation indicate that the subscribers are persons of good character?_____If not, explain. _____
_____
_____
_____
_____

4. From your investigation, is it your judgment that the directors and committee members are persons of good character, and that they have the ability and determination to operate a credit union satisfactorily?_____If not, explain. _____

_____
_____
_____
_____

5. Does it appear that there are any factions within the group which may render smooth and efficient credit union operations difficult?_____If so, explain. _____

_____
_____
_____
_____

6. Is there any indication that the proposed credit union would be used for selfish gain by any person or group of persons within the group to be served?_____

_____
_____
_____
_____

7. Is an application for a State Charter now pending? _____

8. Has the group ever had a credit union?_____If so, when did it liquidate or merge? _____

ANY ADDITIONAL COMMENTS OR INFORMATION THAT IS DEEMED PERTINENT OR HELPFUL IN GIVING CONSIDERATION TO THIS APPLICATION SHOULD BE INCLUDED AS AN ATTACHMENT.

The undersigned certifies that to the best of their knowledge and belief the above information is true and correct.

I do (do not) recommend that a charter be granted to this group.

Signature:_____, Organizer
Organizer's Address: _____
_____
_____

Telephone No.:_____Date: _____

FORM 4001 INSTRUCTIONS

A. INFORMATION FOR CHARTER AND BYLAWS

The subscriber should select a name for the proposed credit union. It is the responsibility of the federal credit union organizers to ensure that the proposed federal credit union name does not constitute an infringement on the name of any corporation in its trade area. The last three words in the name must be "Federal Credit Union." Since the name selected should not duplicate exactly the name of an existing credit union, Item 1 provides space for a second choice.

The territory of operations of a Federal Credit Union is described in the field of membership, item 4. The principal office of the credit union will usually be maintained at a location described in the field of membership.

The proposed field of membership should be defined so clearly that it leaves no room for any doubt as to whom the credit union is to serve or the area which it is to operate. Corporations and other organizations referred to in the definition of the field of membership should be designated by the exact names rather than by some local or popular contraction of these names. The field of membership for each type of common bond and samples are discussed in detail in Chapter 2 of the "*Chartering and Field of Membership Manual*."

With the guidance of the organizer, the subscribers to the Organization Certificate decide on the number of directors and credit committee members. The board and credit committee must be composed of an odd number of members. The supervisory committee is appointed by the board of directors.

B. ECONOMIC ADVISABILITY OF ORGANIZING PROPOSED CREDIT UNION

This section of the report contains information on the required business plan elements and other information needed to make a decision on the economic advisability of chartering the proposed credit union.

C. CHARACTER AND FITNESS OF SUBSCRIBERS

The names and addresses of the subscribers should be recorded legibly and completely in item C. 1. of this report. It is from this information that the National Credit Union Administration prepares Section 3 of the charter. The names of the subscribers must be IDENTICAL to their signatures on the Organization Certificate.

D. SUBMITTAL OF CHARTER APPLICATION

In addition to this Investigation Report, the following should be submitted to the Director of NCUA's Office of Consumer Financial Protection and Access:

1. Organization Certificate, NCUA 4008 - one notarized original. At least seven, *but no more than ten persons*, must sign the organization certificate. The person administering the oath must not be one of the subscribers. The oath on the organization certificate must be executed and show the notary's seal and date the commission expires as required by State law;

2. Report of Official and Agreement to Serve, NCUA 4012 – one original for each board member, credit committee member, and supervisory committee member;

3. Business Plan - refer to Part B, question 4 of this form and Chapter 1 of the *Chartering and Field of Membership Manual* for a discussion of the components of an acceptable business plan;

4. Application and Agreements for Insurance of Accounts, NCUA 9500 - one original; and

5. Certification of Resolutions, NCUA 9501 - one original.

~~1.~~

NATIONAL CREDIT UNION ADMINISTRATION

_____

FEDERAL CREDIT UNION

(A corporation chartered under the laws of the United States)

CHARTER NO. _____

NCUA 4008
PAGE 1

ORGANIZATION CERTIFICATE

_____FEDERAL CREDIT UNION

Charter No. _____

TO NATIONAL CREDIT UNION ADMINISTRATION:

We, the undersigned, do hereby associate ourselves as a Federal Credit Union for the purposes indicated in and in accordance with the provisions of the Federal Credit Union Act, (12 U.S.C. 1751 et seq.). We hereby request approval of this organization certificate; we hereby apply for insurance of member accounts; we agree to comply with the requirements of said Act, with the terms of this organization certificate and with all laws, rules, and regulations now or hereafter applicable to Federal Credit Unions.

(1) The name of this credit union shall be_____Federal Credit Union.

(2) This credit union will maintain its office and will operate in the territory described in the field of membership.

(1)

(3) The names and addresses of the subscribers to this certificate and the number of shares subscribed by each are as follows:

NAME	ADDRESS	SHARES

(4) The par value of the shares of this credit union will be stated in the bylaws.

(5) The field of membership shall be limited to those having the following common bond:_____

_____

_____

_____

_____

_____

_____

(6) The term of this credit union's existence shall be perpetual: Provided, however, that upon the finding that this credit union is bankrupt or insolvent or has violated any provision of this organization certificate, of the bylaws, of the Federal Credit Union Act including any amendments thereto or thereof, or of any regulations issued thereunder, this organization certificate may be suspended or revoked under the provisions of Section 120(b) of the Federal Credit Union Act.

(7) This certificate is made to enable the undersigned to avail themselves of the advantages of said Act.

(8) The management of this credit union, the conduct of its affairs, and the powers, duties, and privileges of its directors, officers, committees and membership shall be set forth in the approved bylaws and any approved amendments thereto or thereof.

IN WITNESS THEREOF we[1] have here unto subscribed our names this

_____ _____ _____
(day) (month) (year)

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Subscribed before me, an officer competent to

administer oaths, at _____
CITY/STATE

this _____ _____ _____
(day) (month) (year)

Signed _____

Title_____
(Notary public or other competent officer)

1 At least seven signers none of whom should administer the oath.

APPROVAL OF ORGANIZATION CERTIFICATE
AND
CERTIFICATION OF INSURANCE

Pursuant to the provisions of the Federal Credit Union Act (12 U.S.C. 1751 et seq.), the foregoing organization certificate and insurance of member accounts of _____Federal Credit Union are approved this

_____ _____ _____
(day) (month) (year)

_____
CHAIRPERSON
NATIONAL CREDIT UNION ADMINISTRATION

REPORT OF OFFICIAL AND AGREEMENT TO SERVE

TO: NATIONAL CREDIT UNION ADMINISTRATION

Proposed_____Federal Credit Union

Title of Prospective Position:_____

Name:_____
Mr./Ms./Mrs. Last, First, Middle

Maiden Name (If Different From Above): _____

Address (Res.): _____
Street, City, State, Zip Code

Telephone Number: (___)_____

Place of Birth:_Date of Birth:_____City/State/Country

Employer: _____

Social Security Number (Optional): _____

Type of Business: _____

Number of years with present employer:_____Your position title: _____

Education background (enter highest grade completed)
High School:_____College:_____Major Field of Study: _____

Other training or experience:

_____
_____
_____
_____

Are you willing to accept the position of trust for which you have been selected and to remain in office until a qualified successor is found?_____YES_____NO

Have you been informed as to the general duties and responsibilities of an official of the proposed Federal Credit Union and are you willing to devote the time

necessary to familiarize yourself with and to perform your duties?

Estimated number of hours per month you will be able to volunteer:_____

IF THE ANSWER IS YES TO THE FOLLOWING QUESTION, PLEASE PROVIDE INFORMATION AS INSTRUCTED ON THE FOLLOWING PAGE:

Have you ever been convicted of any CRIMINAL OFFENSE involving dishonesty or a breach of trust?____YES_____NO

To facilitate the process of obtaining a credit and background check, please provide the following:

1. **Any other names which you have used:_____and,**
2. **Previous address, (if your address changed over the past 2 years):**

   _____

   _____

   _____

3. **Name of Spouse: _____**

READ THE FOLLOWING CAREFULLY BEFORE SIGNING

CERTIFICATION AND AGREEMENT TO SERVE

I certify that the information provided on this form is true and correct. Further, I, the undersigned, having been duly designated to occupy the position(s) indicated above, do hereby agree to serve in the above-stated office(s) of this proposed credit union until the first annual meeting held in accordance with the Federal Credit Union Act and the bylaws of this credit union and until the election of my successor(s). I further pledge to carry out the duties and responsibilities commensurate with said office(s) as promulgated by the Federal Credit Union Act and the bylaws of this credit union. I have read the Privacy Act Notice that follows.

Date	Signature	Witness

PRIVACY ACT NOTICE

The Privacy Act of 1974 (Public Law 93-579) requires that you be advised as to the legal authority, purpose and uses of the information solicited by this form. Pursuant to Sections 104 and 205(d) of the Federal Credit Union Act, the information in this form is requested for the purpose of completing the investigation required for a new Federal credit union. The information in this form will be primarily used in considering the soundness of the management for the proposed Federal credit union. However, this form may be disclosed to any of the following sources: a congressional office in response to your inquiry to that office; an appropriate Federal, state or local authority in the investigation or enforcement of a statute or regulation; or employees of a Federal agency for audit purposes. Failure to complete this form or omission of any item of information, except for disclosure of your social security number, may result in a delay in the process for chartering the proposed Federal credit union. In accordance with Section 792.68 of NCUA's regulations, you are not required to furnish your social security number on this form. Your social security number, if voluntarily provided, will be used to more easily verify the information required by this form.
No penalty will result to you as a management official or to the chartering of the proposed Federal credit union if you do not provide your social security number.

Further information needed if answer to CRIMINAL OFFENSE question on the previous page was YES:

CRIMINAL OFFENSE:

Nature of offense: ____
_____
Date of occurrence:_____Date of conviction: _____
Sentence conferred: _____
(Attach a separate sheet if space provided is not adequate)

CRIMINAL OFFENSE GUIDELINES

The Federal Credit Union Act, Subchapter II, Section 205(d), requires that, except with the written consent of the NCUA Board, no person shall serve as director, officer, committee member, or employee of an insured credit union who has been convicted or who is hereafter convicted, of any criminal offense involving dishonesty or breach of trust. To assist the NCUA Board in making a determination of the fitness of a person who is selected to serve and who the organizer believes is qualified to serve as an official, the specific information above will need to be furnished.

If the NCUA Board believes that, in view of the facts presented and the date of the offense, they can give their consent to the appointment they will so advise that person in writing. If on the other hand, the NCUA Board believes after careful consideration that they cannot in good conscience give their written consent to the appointment they will contact the organizer and ask that another person be selected for the position. The person selected will have to complete a Report of Official and Agreement to Serve.

An indication of whether the bonding company would agree to provide coverage should be included if the person is to serve as treasurer. Bonding company agrees to provide coverage:____YES_____NO

AUTHORIZATION TO OBTAIN A CREDIT REPORT

The National Credit Union Administration (NCUA) may evaluate the competence, experience, character, and integrity of any individual who is to serve as an official, employee, or committee member of a federally insured credit union, in accordance with §1790a of the Federal Credit Union Act and Chapter 1, §V.B.4 of the NCUA Chartering and Field of Membership Manual.

NCUA may disapprove any individual whose employment it believes will not be in the best interest of the credit union or of the public. To assist in the evaluation process, NCUA may obtain and review an individual's credit report.

Your signature on this document authorizes NCUA to obtain a copy of your credit report.

_____

Last **First** **Middle**

Social Security Number: _____

Date of Birth: _____

_____

Signature **Date**

APPLICATION FOR FIELD OF MEMBERSHIP AMENDMENT
NCUA FORM 4015

USE FOR MULTIPLE COMMON BOND EXPANSION FOR GROUPS OF 5,000 OR MORE PERSONS

Attach a separate application for each group included in your request for expansion. The application must be complete or it will be returned unprocessed.

1. Name and address of credit union: _____ _____ _____ Telephone Number: _____ Charter Number: _____

2. Name and address of group: _____ _____ _____ Telephone Number: _____

If the group is an association:

☐ ***Include a statement indicating whether the association has been formed primarily for the purpose of expanding credit union membership. Such a group is not eligible for inclusion in a multiple common bond credit union unless it qualifies as a low-income association; and***

If the group is an association AND it is NOT one of the categories of pre-approved groups outlined in Chapter 2, Section III.A.1.b of the Chartering Manual:

☐ ***Include a copy of the association's Charter/Bylaws or other equivalent organizational documentation.***

3. Provide the proposed field of membership wording. Use the example wording found in NCUA's *Chartering and Field of Membership Manual,* Chapter 2, Section IV.A.2.

_____
_____
_____

4. How many primary potential members (excluding immediate family and household members) are in the group:

_____

5. (a) What is the distance between the group's location and your credit union's nearest service facility[1] to which the group has access (Reference Chapter 2, Section IV.A.1):

_____

_____

(b) What is the address of this service facility:

_____

_____

_____

(c) Describe the service area[2] primarily served by the above service facility:

_____

_____

_____

_____

6. Is the group in the field of membership of <u>any</u> other credit union? Yes____ No____

If yes, and the overlapped credit union is not a community credit union or a non-federally insured credit union, please address the following:

☐ Provide the name and location of the other servicing credit union:

_____

_____

_____

☐ Include a letter from the overlapped credit union indicating whether it concurs or objects to the overlap. If the overlapped credit union objects or fails to respond, document attempts to resolve the issue:

_____

_____

_____

_____

[1] **A service facility is defined as a place where shares are accepted for members' accounts, loan applications are accepted or loans are disbursed.**

[2] **A federal credit union's service area is the area that can reasonably be served by the service facility accessible to the groups within the field of membership. It will most often coincide with that geographic area primarily served by the service facility.**

☐ Explain how the expansion's beneficial effect in meeting the convenience and needs of the members of the group clearly outweighs any adverse effect on the overlapped credit union:

_____
_____
_____
_____

7. Attach a letter, or equivalent documentation, from the group requesting credit union service indicating:

☐ that the group wants to be added to the federal credit union's field of membership;
☐ whether the group presently has other credit union service available;
☐ the number of persons currently included within the group to be added and the group's location(s);
☐ the group's proximity to the credit union's nearest service facility; and
☐ why the formation of a separate credit union for the group is not practical. The criteria for demonstrating formation of a separate credit union is not practical are outlined in Chapter 2, Section IV.B.2 of NCUA's Chartering and Field of Membership Manual.

8. Other comments:

_____
_____
_____
_____
_____
_____

Name and title of credit union board-authorized representative (e.g., President/CEO):

_____	_____	_____
(Typed/Printed Name)	(Signature)	(Date)

APPLICATION FOR FIELD OF MEMBERSHIP AMENDMENT
NCUA FORM 4015-A

USE FOR MULTIPLE COMMON BOND EXPANSION FOR GROUPS OF 3,000 to 4,999 PERSONS

Attach a separate application for each group included in your request for expansion. The application must be complete or it will be returned unprocessed.

1. Name and address of credit union: Telephone Number: _____
   _____ Charter Number: _____
   _____
   _____

2. Name and address of group: Telephone Number: _____
   _____
   _____
   _____

If the group is an association:

☐ ***Include a statement indicating whether the association has been formed primarily for the purpose of expanding credit union membership. Such a group is not eligible for inclusion in a multiple common bond credit union unless it qualifies as a low-income association; and***

If the group is an association AND it is NOT one of the categories of pre-approved groups outlined in Chapter 2, Section III.A.1.b of the Chartering Manual:

☐ ***Include a copy of the association's Charter/Bylaws or other equivalent organizational documentation.***

3. Provide the proposed field of membership wording. Use the example wording found in NCUA's *Chartering and Field of Membership Manual*, Chapter 2, Section IV.A.2.

   _____
   _____
   _____

4. How many primary potential members (excluding immediate family and household members) are in the group:

_____

5. (a) What is the distance between the group's location and your credit union's nearest service facility1 to which the group has access (Reference Chapter 2, Section IV.A.1):

(b) What is the address of this service facility:

_____
_____
_____

(c) Describe the service area[2] primarily served by the above service facility:

_____
_____
_____
_____

6. Attach a letter, or equivalent documentation, from the group requesting credit union service indicating:

- ☐ that the group wants to be added to the federal credit union's field of membership;
- ☐ the number of persons currently included within the group to be added and the group's location(s);
- ☐ how the group is within reasonable proximity to the credit union; and the
- ☐ formation of a separate credit union for the group is not practical.

Include a statement indicating the formation of a separate credit union is not practical because the group lacks available subsidies, interest among the group's members, and sufficient resources. No additional information or documentation is necessary.

---

[1] **A service facility is defined as a place where shares are accepted for members' accounts, loan applications are accepted or loans are disbursed.**

[2] **A federal credit union's service area is the area that can reasonably be served by the service facility accessible to the groups within the field of membership. It will most often coincide with that geographic area primarily served by the service facility.**

7. Other comments:

_____
_____
_____
_____
_____
_____

Name and title of credit union board-authorized representative (e.g., President/CEO):

_____	_____	_____
(Typed/Printed Name)	(Signature)	(Date)

APPLICATION FOR FIELD OF MEMBERSHIP AMENDMENT
NCUA FORM 4015-EZ

USE FOR MULTIPLE COMMON BOND EXPANSIONS OF LESS THAN 3,000 PERSONS AND ALL SINGLE COMMON BOND EXPANSIONS

Attach a separate application for each group included in your request for expansion. The application must be complete or it will be returned unprocessed.

1. Name and address of credit union: _____ _____ _____ Telephone Number: _____ Charter Number: _____

2. Name and address of group: _____ _____ _____ Telephone Number: _____

If the group is an association:

☐ ***Include a statement indicating whether the association has been formed primarily for the purpose of expanding credit union membership. Such a group is not eligible for inclusion in a multiple common bond credit union unless it qualifies as a low-income association; and***

If the group is an association AND it is NOT one of the categories of pre-approved groups outlined in Chapter 2, Section III.A.1.b of the Chartering Manual:

☐ ***Include a copy of the association's Charter/Bylaws or other equivalent organizational documentation.***

3. Provide the proposed field of membership wording:_____ _____ _____

4. **Multiple Common Bond Expansions Only:** Attach a letter, or equivalent documentation, from the group requesting credit union service indicating:

☐ that the group wants to be added to the federal credit union's field of membership;

☐ the number of persons to be added and the group's location(s); and

☐ the group's distance to the credit union's nearest service facility.

5. **Single Common Bond Expansions Only:** How the group shares the occupational or associational common bond_____

6. How many primary potential members (excluding immediate family and household members) are in the group: _____

Name and title of credit union board-authorized representative (e.g., President/CEO):

_____	_____	_____
(Typed/Printed Name and Title)	(Signature)	(Date)

NOTICE OF MEETING OF MEMBERS TO CONVERT FROM A FEDERAL TO A STATE CHARTERED CREDIT UNION

_____FEDERAL CREDIT UNION

_____ _____
(City) (State)

THIS PROPOSITION WILL BE DECIDED BY A MAJORITY OF THE MEMBERS WHO VOTE.

Notice is hereby given that a meeting of the members of _____ Federal Credit Union has been called and will be held at_____ _____on_____, at_____o'clock, .M. for the purpose of considering and voting upon the following resolution:

> **"RESOLVED, That the_____Federal Credit Union be converted to a credit union chartered under the laws of the State of _____and that its operation under Federal charter be discontinued.**
>
> **RESOLVED FURTHER, That the board of directors and the officers of this credit union and are hereby authorized and directed to do all things necessary to effect and to complete the conversion of this credit union from a Federal to State-chartered credit union."**

The board of directors of this credit union has given careful consideration to the advantages and the disadvantages of the proposed conversion and believes it to be in the best interest of the members for the following reasons:

The proposed conversion would result in the following disadvantages or adverse changes in services and benefits to the members of the credit union:

The proposed conversion would result in the following costs of conversion (i.e. changing the credit unions name, examination and operating fees, attorney and consulting fees, tax liability, etc.):

The board of directors recommends that the members approve the proposal to convert to a State charter.

The members' accounts will ☐ will not ☐ continue to be insured by the National Credit Union Share Insurance Fund.

Attached is your ballot. You are urged to bring your ballot to the meeting and to cast your vote after hearing the discussion of the proposal. If you cannot attend the meeting, you are urged to mark your vote, date and sign your ballot, and return it to the following address by no later than the date and the time announced for the meeting of the members:

BY ORDER OF THE BOARD OF DIRECTORS

_____
TITLE: _____
(CHAIRPERSON)

_____
TITLE: _____
(BOARD SECRETARY)

Issued _____(Date)

APPLICATION TO CONVERT FROM A STATE TO A FEDERAL CREDIT UNION

The_____Credit Union of_____(city),_____(State), incorporated under the laws of the State of_____on_____by decision of its board of directors, hereby makes application to the National Credit Union Administration to convert to a Federal credit union.

1. **Field of membership. Provide a copy of the credit union's charter, articles of incorporation or bylaws, as amended to date.**

   _____
   _____
   _____

2. **Is proposed Federal charter to cover same field of membership? Yes ☐ No ☐ If answer is "No," explain fully: _____**

   _____
   _____
   _____

3. **Standard financial and statistical reports as of_____or comparable forms of reports, certified correct by the treasurer and verified by the affidavit of the president or vice-president, are attached.**

4. **A schedule of delinquent loans classified 2 to 6 months, 6 to 12 months, and 12 months and over delinquent is attached.**

5. **The following policies on loans to members are currently in effect in this credit union:**

   a. Interest rates on loans: _____

   b. Charges incident to making loans which are passed on to borrowers: _____

   c. Maturity limits: _____

   d. Unsecured loan limit: _____

   e. Secured loan limit: _____

   f. Types of security accepted: _____

   g. Requirements of amortization (Repayment requirements): _____

6. **Attached is a list of unsecured loans in excess of the amounts stipulated in the Act. (For each loan show account number, original amount, terms, and unpaid balance.)**

1.

7. **Attached is a list of loans with maturities in excess of periods stipulated in the Act and the NCUA Rules and Regulations. (For each loan show account number, original amount, terms, unpaid balance, and security.)**

8. **Types of accounts which members are required or are permitted to maintain:**
   Share ☐ Deposit ☐ Other ☐ (describe): _____
   _____
   _____

9. **Describe any real estate owned by credit union, including a list of its current market value: _____**
   _____
   _____

10. **Describe and list any investments which are outside of the investment powers of Federal credit unions (Refer to Section 107(7), Federal Credit Union Act):_____**
    _____
    _____

11. **Names and locations of any depository institutions in which the credit union deposits its funds but which are beyond the purview of deposit powers authorized by Section 107(8) of the Federal Credit Union Act: _____**
    _____
    _____

12. **Describe any services rendered to or on behalf of members or of the public, other than accepting and maintaining accounts of members and making loans to members: _____**
    _____
    _____

13. **Describe what you propose to do about any policies, procedures, assets or liabilities which do not comply with the Federal Credit Union Act: _____**
    _____
    _____

14. **Give specific reasons as to why you desire to convert to a Federal credit union:**
    _____
    _____

We hereby authorize the National Credit Union Administration to examine our books and our records.

We, the undersigned _____ Chief Executive Officer and _____ Chief Financial Officer of the _____ Credit _____ of _____ State of _____ certify: That we are the duly elected Chairperson and the Chief Financial Officer, respectfully, of said credit union; that the statements made in this Application to Convert from a State to a Federal Credit Union and the schedules attached hereto are true, complete, and correct to the best of our knowledge and belief and are made in good faith.

_____
TITLE: _____
(CHAIRPERSON)

_____
TITLE: _____
(CHIEF FINANCIAL OFFICER)

AFFIDAVIT
PROOF OF RESULTS OF MEMBERSHIP VOTE - PROPOSED CONVERSION FROM FEDERAL CREDIT UNION TO STATE CREDIT UNION

We, the undersigned_____chairperson and _____secretary of the _____ Federal Credit Union, hereby swear or affirm as follows:

1. **That the conversion proposal as set forth in the attached Notice of Meeting of the Members was fully explained to the members present at said meeting of members.**

2. **That on the date of the said meeting of members there were_____members of this credit union qualified to vote;_____members were present at said meeting; of those members present,_____members voted in favor of the conversion and_____members voted against the conversion; of those members not present at the meeting but who filed ballots,_____members voted in favor of the conversion and_____members voted against the conversion; and that, without duplication of the votes of any member, a total of_____members voted in favor of the conversion and_____members voted against the conversion.**

~~1.~~

3. That the action of the members of this credit union at said meeting is fully and completely recorded in the minutes of said meeting and all ballots cast by the members on the question of conversion, either at the meeting or by delivery to the credit union, are on file with the secretary of this credit union.

_____
TITLE: _____
(CHAIRPERSON)

_____
TITLE: _____
(BOARD SECRETARY)

_____
FEDERAL CREDIT UNION

Subscribed before me, an officer competent to administer oaths, at _____
_____, this _____
(day) (month) (year)

Signed _____

(SEAL)

Title _____

(Notary Public or other competent officer)

My Commission Expires_____, _____
(year)

FEDERAL TO STATE CONVERSION

BALLOT FOR CONVERSION PROPOSAL

I have read the notice concerning the meeting of the members of the _____Federal Credit Union called for_____to consider and to vote upon the following proposition:

> "RESOLVED, That the_____Federal Credit Union be converted to a credit union chartered under the laws of the State of_____and operation under Federal Charter Number_____be discontinued.
>
> RESOLVED FURTHER, That the board of directors and the officers of this credit union are hereby authorized and directed to do all things necessary to effect and to complete the conversion of this credit union from a Federal to State-chartered credit union."

I hereby cast my vote on the proposition: (Place an X in the square opposite the appropriate statement.)

I vote for the conversion ☐

I vote against the conversion ☐

_____ _____

(Account Number) (Signature of Member)

Date: _____

NCUA 4506

APPLICATION AND AGREEMENTS FOR INSURANCE OF ACCOUNTS

Date: _____

TO: The National Credit Union Administration Board (Board)

The proposed_____Federal Credit Union

_____
(Street Address)

_____
(City) (State) (Zip Code)

applies for insurance of its accounts as provided in Title II of the Federal Credit Union Act, and in consideration of the granting of insurance, hereby agrees:

1. **To pay the reasonable cost of such examinations as the Board may deem necessary in connection with determining the eligibility of the application for insurance.**

2. **To permit and pay the reasonable cost of such examinations as in the judgment of the Board may from time to time be necessary for the protection of the fund and other insured credit unions.**

3. **To permit the Board to have access to any information or report with respect to any examination made by or for any public regulatory authority and furnish such additional information with respect thereto as the Board may require.**

4. **To provide protection and indemnity against burglary, defalcation, and other similar insurable losses, of the type, in the form, and in an amount at least equal to that required by the laws under which the credit union is organized and operates.**

5. **To maintain such special reserves as the Board, by regulation or in special cases, may require for protecting the interest of members.**

6. **Not to issue or have outstanding any account or security the form of which, by regulation or in special cases, has not been approved by the Board.**

7. **To pay and maintain the capitalization deposit required by Title II of the Federal Credit Union Act.**

8. **To pay the premium charges for insurance imposed by Title II of the Federal Credit Union Act.**

~~1.~~

9. To comply with the requirements of Title II of the Federal Credit Union Act and of regulations prescribed by the Board pursuant thereto.

10. To permit the Board to have access to all records and information concerning the affairs of the credit union and to furnish such information pertinent thereto that the Board may require.

11. To comply with Title 18 of the United States Code and other pertinent Federal statutes as they may exist or may be hereafter promulgated or amended.

We, the undersigned, certify to the correctness of the information submitted. We, the undersigned, further certify that to the best of our knowledge and belief no proposed officer, committee member, or employee of this credit union has been convicted of any criminal offense involving dishonesty or a breach of trust, except as noted in attachments to this application. We further agree to notify the Board if any proposed or future officer commits a criminal offense.

Chairperson	**Chief Financial Officer**

Note: A willfully false certification is a criminal offense. U.S. Code, Title 18, Sec. 1001.

CERTIFICATION OF RESOLUTIONS

_____FEDERAL CREDIT UNION (PROPOSED)

We certify that we are the duly elected and qualified chief executive officer and recording officer of the above-named proposed Federal credit union and that at the charter-organization meeting, the board of directors passed the following resolution and recorded it in its minutes:

> **"Be it resolved that this credit union apply to the National Credit Union Administration Board for insurance of its accounts as provided in Title II of the Federal Credit Union Act.**
>
> **Be it further resolved that the president and treasurer be authorized and directed to execute the Application and Agreements for Insurance of Accounts as prescribed by the Board and any other papers and documents required in connection therewith; to pay all expenses and do all other things necessary or proper to secure and continue in force such insurance."**

_____

Chief Executive Officer

_____

Recording Officer, Board of Directors

INFORMATION TO BE PROVIDED IN SUPPORT OF THE APPLICATION OF A STATE CHARTERED CREDIT UNION FOR INSURANCE OF ACCOUNTS

Existing credit unions must complete the entire application. All other applicants do not have to complete questions 8, 11, 12, 13, 15, and 16.

_____Credit Union

1. **Show below the location of the credit union's books and records.**

   _____
   (Street Address)

   _____
   (City) (State) (Zip) (Telephone)

2. **Show the date (month, day, year) in which the credit union was chartered.**
   _____

3. **Attach a copy of the credit union's field of membership as shown in the charter, articles of incorporation and/or bylaws, as amended to date. Please identify it as the first schedule in the consecutive number sequence as discussed in the instructions. Schedule No. _____**

4. **Potential membership (total number of persons who could be served including present members). _____**

5. **Identify charter type (e.g., single common bond, multiple common bond, community). _____**

6. **Does the credit union operate under standard bylaws provided by the state supervisory authority? Yes ☐ No ☐ (Complete a.)**

   a. Attach a copy of the current official bylaws under which the credit union operated. Schedule No. _____

7. **Is the credit union under any administrative restraints by the State Supervisory Authority? Yes ☐ No ☐ (Complete a.)**

   a. Explain fully on an attached schedule. Schedule No. _____
   a.

8. **Attach a copy of the latest State supervisory authority examination. Copies of any correspondence from the accountant's report if made in lieu of a State supervisory authority examination. Copies of any correspondence from the State supervisory authority which accompanied the examination report should also be included.**

9. **Attach copies of the Balance Sheet and Statement of Income and Expense (or Financial and Statistical Report) for the month preceding the date of this application and for the same month of the preceding year.**
Schedule Nos. _____

10. **Reserves**

Show below the requirements of the State law and/or your bylaws for transfer of earnings to reserves (either monthly or at the end of each accounting period).

_____

11. **Delinquent Loans and Charged-off Loans**

a. Attach a copy of the delinquent loan list as of the month-end preceding the date of this application. See instructions pertaining to Item No. 11a.
Schedule No. _____

b. List below the requested information on delinquent loans for the latest four calendar quarters preceding the date of the application (March 31, June 30, September 30 and December 31). Also show total share and loan balances for all members for the same period.

(a) *Other Delinquent Categories	(b) Delinquent Categories	Date	Date	Date	Date
	2 to less than 6 mos.	$	$	$	$
	6 to less than 12 mos.	$	$	$	$
	12 mos. and over	$	$	$	$
	Totals	$	$	$	$
	Share Balances	$	$	$	$
	Loan Balances	$	$	$	$

***See instructions pertaining to Item No. 11 b.**

c. List below the requested information on loans charged off during the last three years and the current year. List total of all reserves both revocable and irrevocable for the same period as (balance at year-end and or current period).

	Year	Year	Year	Current Yr. To Date	*Totals Since Organization
Total Charged Off					
Total Recovered					
Net Charged Off					

***If this information is available.**

12. Does the credit union have any unrecorded or contingent liabilities, (including pending law suits or civil actions)? Yes ☐ No ☐ Complete a.

a. List on an attached schedule the complete description of such liabilities, including amounts, status of the items, and a description of the circumstances creating the liabilities or contingent liabilities. Schedule No. _____

13. Do any asset accounts other than loans to members, investments, and real estate have actual values less than the book values shown on the Balance Sheet?

List on a separate schedule a description of such assets, showing at least the following information; account number, description of item, book value and actual value. Schedule No. _____

14. List below or on an attached schedule, any investments or real estate as discussed in the instructions pertaining to Item No. 14. Schedule No._____. Attach a copy of the credit union's current investment policies. Investments/Loans to Credit Union Service Organization (CUSO) should be listed separately.

Description of Item	Current Market Value	Current Book Value
	$	$
	$	$
	$	$

15. Individual Share and Loan Ledgers:

a. Were the totals of the trial balance of the individual share and loan ledgers in agreement with the balances of the respective general ledger control accounts as of the month-end preceding the date of this application? _____

b. What are the differences as of the month and preceding the date of this application?

	Shares	Loans
Balances in General Ledger	$	$
Totals of the trial balance of the individual ledgers	$	$
Differences	$	$

16. Supervisory Committee:

a. What is the effective date of the last complete comprehensive annual audit performed by the supervisory committee?
Effective Date _____

(1) If the effective date of the annual audit is not within the last 18 months what is the supervisory committee's target date for completion of a comprehensive audit? Date _____

b. Show the effective date of the supervisory committee's last controlled verification of all members' accounts:
Effective Date _____

(1) If all members' accounts have not been verified under controlled conditions during the last two years, what is the supervisory committee's target date for completion of the verification program?
Date _____

c. If it is necessary to complete either 16a(1) or 16 b(1); please describe the directors' plans for seeing that the target dates are met. (Discuss below or on an attached schedule.) Schedule No. _____

a.

17. List below the credit union's surety bond coverage.

a. Name of carrier _____

b. Standard form number of the bond (i.e., 23, 576, 577, 578, 581, 562 CU-1, other) _____

c. Basic amount of coverage $_____

d. Bond premium paid to (date) _____

e. What is the amount of coverage required by State law or your bylaws? _____

f. Riders to the bond (list below) (i.e., faithful performance, forgery, misplacement, etc.)

_____

_____

18. Does the credit union render any services to or perform any functions on behalf of the members, non-members, organizations, or the public other than the usual savings and loan services for members? _____

Attach a schedule describing each activity in full. Schedule No. _____

19. Does the board of directors or management know of any adverse economic condition that is affecting or will affect the credit union's present or future operation or that of the sponsor organization? _____

Attach a schedule describing the condition and its possible effect on the credit union's future. Schedule No. _____

20. To the best of the credit union's knowledge and belief, has any director, officer, committee member, or employee been convicted of any criminal offense involving dishonesty or breach of trust? _____

a. Attach a statement describing the circumstances. Schedule No. _____

21. Lending policies and practices:

a. Complete the following schedule showing the present policies and practices on loans to members.

b. Complete the following schedule of largest loans with the attached instructions pertaining to Item No. 21.

a.

LENDING POLICIES AND PRACTICES

	Maximum Loan Amount	Maximum Period of Repayment	Required Amount of Down Payment (Equity)
1. Credit Union Policies and Practices			
a. Unsecured Loan Limits			
b. Secured Loan Limits			
(1) New Auto Collateral			
(2) Used Auto Collateral			
(3) Real Estate			
(a) First Mortgage			
(b) Second Mortgage			
(4) Comakers			
(5) Others (describe)			
c. Loans to Organizations			
d. Loans to Directors, Officers, or Committee Members			
2. State Credit Union Law; Bylaws			
a. Unsecured Loan Limits			
b. Secured Loan Limits			
c. Loans to Directors, Officers, or Committee Members			

List on an attached page, any additional policies, including the interest rates applied to members' loans and the method of assessing and accounting for interest income, i.e.: add-on, discount or unpaid balance.

SCHEDULE OF LARGEST LOANS

Complete this form as discussed in the instructions pertaining to Item 21b.

Account No.	Unpaid Bal.	Repayment Period (Mths)	Repayment Status		Appraised Collateral Value*	Collateral Description
			Current	Mths Delq.		

***If there is more than one type of collateral assign value to each type.**

CREDIT UNION SERVICE ORGANIZATION (CUSO)

1. Name of CUSO _____

2. Date of CUSO'S Organization _____
   (Date of obtaining charter from State)

3. Type of organization (check one):

   a. General Partnership ☐ c. Joint Ownership ☐

   b. Limited Partnership ☐ d. Corporation ☐

4. Owners of CUSO (list name, charter number if FCU, and percentage of ownership, if possible).

   a. _____ _____ _____
   Name Charter Number (If FCU) %

   b. _____ _____ _____
   Name Charter Number (If FCU) %

   (Continue on reverse side if additional space is required)

5. Capitalization (list investors and amount of investment in CUSO).

   a. _____ _____ _____
   Name Charter Number (If FCU) Amount

   b. _____ _____ _____
   Name Charter Number (If FCU) Amount

   (Continue on reverse side if additional space is required)

6. List all known services which are being offered by CUSO (be as specific as possible)._____
_____
_____

7. Comments (include all other pertinent information, if applicable, not previously discussed). _____

_____

_____

_____

8. Attach the latest Financial and Statistical Report of CUSO, if available.

1.

FORM 9600 INSTRUCTIONS

APPLICATION OF A STATE CHARTERED CREDIT UNION FOR INSURANCE OF ACCOUNTS

The application and all supporting documents should be prepared, photocopied, and submitted in accordance with these instructions. Additional schedules may be included if deemed appropriate.

Existing credit unions must complete the entire application. All other applicants do not have to complete questions 8, 11, 12, 13, 15, and 16.

Existing credit unions must submit current policies and financial statements as noted in the application. All other applicants must submit proposed policies and pro forma financial statements for the first and second year of operation.

When an item specifies that a schedule should be prepared and attached, please assign a schedule number in consecutive order, starting with number one. Please show the schedule number at the top right-hand corner of the schedule.

Some of the items are self-explanatory and require no special instructions. Other items, however, need special explanations, definitions, and instructions for completion. These are listed below, identified by the same item numbers as appear in Exhibit A.

Item No. 10: Reserves: The term "reserves" means that account, or accounts, which represents segregated portions of earnings as provided by the law, bylaws, and/or the credit union's management for the absorption of losses relating to loans to members.

Item No. 11a: The delinquent loan list requested should include, for each delinquent loan, the account number of the borrower, date of loan, original amount of loan, unpaid balance, date of last payment of principle, excluding transfers from pledged shares, collateral, and comments regarding the collectibility of each loan in the categories 6 months to less than 12 months and 12 months and over. Payments of interest only should be so identified.

Item No. 11b: The schedule provided for the delinquent loan information is set up in delinquency categories of 2 months to less than 6 months, 6 to less than 12 months, and 12 months and over. Credit unions that compute delinquency using categories other than shown in column (b) may use these other categories and show them in column (a). Credit unions using column (a) need not show the delinquencies in the column (b) categories. It is not necessary to report on loans which are delinquent less than 2 months.

Adverse Trends: If items 8, 9, or 11 indicate adverse trends such as significant decreases in shares, loans or reserves, increases in loan delinquency or loan charge-offs, or unresolved serious exceptions shown in the State examination report, the credit union may attach an explanation and identify it as "Explanation of Adverse Trends or Unresolved

Examination Exceptions" and assign it a schedule number.

Item No. 14: This item need be

completed only if the credit union owns any of the following:

A. Investments in U.S. Government securities guaranteed as to principle and interest or Federal Agency securities, the market value of which is now less than the book value.

B. Real estate other than that used entirely for the credit union's own office(s).

C. Other investments of any type

except:

1. Loans to other credit unions.
2. Certificates of, or accounts in, federally insured financial institutions.
3. Deposits or accounts in corporate credit unions.

If corporate bonds are listed, please show maturity date, rate of interest on bonds and current yield rate.

If stocks are listed, please show number of shares and bid price.

Please identify the source of the market valuation information and the date of such information.

Item No. 21b: In selecting the largest loans for this Exhibit, list the largest outstanding unpaid loan balance and below has been shown. The number of such loans to be listed will be determined as follows:

If your credit union has the following no. of outstanding loans	You should list the following no. of the largest unpaid balances
Under 100	5
100 to 199	10
200 to 299	15
300 to 399	20
400 or more	25

proceed in descending order by dollar amount until the number specified

If any of the above loans are delinquent, please show the number of months delinquent in the appropriate "Status of Re-payment" column.

Complete the Credit Union Service Organization (CUSO) schedule for each investment/loan to a CUSO.

TERMINATION OF INSURANCE

Should the credit union, after obtaining insurance of member accounts, desire to terminate its insured status, this could be accomplished by complying with the provisions of Section 206(a), (c) and (d) of Title II of the Federal Credit Union Act. This action would require approval by a vote of the majority of the members, and ninety days written notice of the proposed termination date to NCUA. Member accounts would continue to be insured for one year following termination of insurance and the insurance premium

would be paid during that period. After termination of insurance, the credit union shall give prompt and reasonable notice to all members whose accounts are insured that it has ceased to be an insured credit union.

Sections 206(a)(2) and 206(d)(2) and (3) of the Act provide that an insured credit union may also terminate its insurance by converting from its status as an insured credit union under the Act to insurance from a corporation authorized and duly licensed to insure member accounts. In this event, approval is required by a majority of all the directors and by affirmative vote of a majority of the members voting, provided that at least 20 percent of the members have voted on the proposition. Under this provision for termination, insurance of member accounts would cease as of the date of termination.

APPLICATION AND AGREEMENTS FOR INSURANCE OF ACCOUNTS
STATE CHARTERED CREDIT UNION

TO: The National Credit Union Administration Board Date _____

The_____Credit Union,

Insurance Certificate Number_____(if applicable)

_____
(mailing address) (city) (state) (zip code)

applies for insurance of its accounts as provided in Title II of the Federal Credit Union Act, and in consideration of the granting of insurance, hereby agrees:

1. **To permit and pay the cost of such examinations as the NCUA Board deems necessary for the protection of the interests of the National Credit Union Share Insurance Fund.**

2. **To permit the Board to have access to all records and information concerning the affairs of the credit union, including any information or report related to an examination made by or for any other regulating authority, and to furnish such records, information, and reports upon request of the NCUA Board.**

3. **To possess such fidelity coverage and such coverage against burglary, robbery, and other losses as is required by Parts 713 and 741 of NCUA's regulations.**

4. **To meet, at a minimum, the statutory reserve and full and fair disclosure requirements imposed on Federal Credit Unions by Part 702 of NCUA's regulations, and to maintain such special reserves as the NCUA Board may be regulation or on a case-by-case basis determine are necessary to protect the interests of members. Any waivers of the statutory reserve or full and fair disclosure requirements or any direct charges to the statutory reserve other than loss loans must have the prior written approval of the NCUA Board. In addition, corporate credit unions shall be subject to the reserve requirements specified in Part 704 of NCUA's regulations.**

5. **Not to issue or have outstanding any account or security the form of which has not been approved by the NCUA Board, except accounts authorized by state law for state credit unions.**

1.

6. To maintain the deposit and pay the insurance premium charges imposed as a condition of insurance pursuant to Title II (Share Insurance) of the Federal Credit Union Act.

7. To comply with the requirement of Title II (Share Insurance) of the Federal Credit Union Act and of regulations prescribed by the NCUA Board pursuant thereto.

8. For any investments other than loans to members and obligations or securities expressly authorized in Title I of the Federal Credit Union Act, as amended to establish now and maintain at the end of each accounting period and prior to payment of any dividend, an Investment Valuation Reserve Account in an amount at least equal to the net excess of book value over current market value of the investments. If the market value cannot be determined, an amount equal to the full book value will be established. When, as of the end of any dividend period, the amount in the Investment Valuation Reserve exceeds the difference between book value and market value, the board of directors may authorize the transfer of the excess to Undivided Earnings.

9. When a state-chartered credit union is permitted by state law to accept nonmember shares or deposits from sources other than other credit unions and public units, such nonmember accounts shall be identified as nonmember shares or deposits on any statement or report required by the NCUA Board for insurance purposes. Immediately after a state-chartered credit union receives notice from NCUA that its member accounts are federally insured, the credit union will advise any present nonmember share and deposit holders by letter that their accounts are not insured by the National Credit Union Share Insurance Fund. Also, future nonmember share and deposit fund holders will be so advised by letter as they open accounts.

10. In the event a state-chartered credit union chooses to terminate its status as a federally-insured credit union, then it shall meet the requirements imposed by Sections 206(a)(1) and 206(c) of the Federal Credit Union Act and Part 741.208 of NCUA's regulations.

11. In the event a state-chartered credit union chooses to convert from federal insurance to some other insurance from a corporation authorized and duly licensed to insure member accounts, then it shall meet the requirements imposed by Sections 206(a)(2), 206(c), 206(d)(2), and 206(d)(3) of the Federal Credit Union Act and any other applicable federal law.

1.

In support of this application we submit the following schedules:

Schedule No.	Title

CERTIFICATIONS AND RESOLUTIONS

We, the undersigned, certify that we are the duly elected and qualified presiding officer and recording officer of the credit union and that at a properly called and regular or special meeting of its board of directors, at which a quorum was present, the following resolutions were passed and recorded in its minutes:

We, the undersigned, certify to the correctness of the information submitted.

Be it resolved that this credit union apply to the National Credit Union Administration Board for insurance of its accounts as provided in Title II of the Federal Credit Union Act.

Be it resolved that the presiding officer and recording officer be authorized and directed to execute the Application and Agreement for Insurance of Accounts as prescribed by the NCUA Board and any other papers and documents required in connection therewith and to pay all expenses and do all such other things necessary or proper to secure and continue in force such insurance.

We further certify that to the best of our knowledge and belief no existing or proposed officer, committee member, or employee of this credit union has been convicted of any criminal offense involving dishonesty or breach of trust, except as noted in attachments to this application. We further agree to notify the Board if any existing, proposed or future officer, committee member or employee is indicted for such an offense.

_____

(Signature) Chairperson, Board of Directors

_____

(Print or type Chairperson's Name)

_____

(Signature) Secretary, Board of Directors

_____

(Print or type Secretary's Name)

APPENDIX 5

TRADE ASSOCIATIONS

Credit Union National Association (CUNA)
www.cuna.org

P.O. Box 431
Madison, WI 53701
800-356-9655

National Association of Federal Credit Unions (NAFCU)
www.nafcu.org

3138 N. 10th Street, Suite 300
Arlington, VA 22201-2149
800-336-4644

National Association of State Credit Union Supervisors (NASCUS)
www.nascus.org

1655 North Fort Myer Drive
Suite 650
Arlington, VA 22209
703-528-8351

National Federation of Community Development Credit Unions (NFCDCU)
www.cdcu.coop

39 Broadway, Suite 2140
New York, NY 10006-3063
212-809-1850

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Part V

Federal Trade Commission

16 CFR Part 315

Contact Lens Rule; Proposed Rule

FEDERAL TRADE COMMISSION

16 CFR Part 315

RIN 3084–AB36

Contact Lens Rule

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: As part of its regulatory review of the Contact Lens Rule (''Rule''), and consistent with the requirements of the Fairness to Contact Lens Consumers Act (the ''Act''), the Federal Trade Commission proposes to amend the Rule to require that prescribers obtain a signed acknowledgment after releasing a contact lens prescription to a patient, and maintain each such acknowledgment for a period of not less than three years. The Commission seeks comment on this proposal and several other issues.

DATES: Written comments must be received on or before January 30, 2017.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Contact Lens Rule, 16 CFR part 315, Project No. R511995'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/contactlensrule* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''Contact Lens Rule, 16 CFR part 315, Project No. R511995'' on your comment and on the envelope and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex C), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex C), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Elizabeth Delaney, Attorney, (202) 326–2903, or Paul Spelman, Attorney, (202) 326–2487, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580.

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I. Background

A. Overview of the Contact Lens Rule

In 2003, Congress enacted the Fairness to Contact Lens Consumers Act,[1] and pursuant to the Act, the Commission promulgated the Contact Lens Rule on July 2, 2004.[2] The Rule went into effect on August 2, 2004.

The Contact Lens Rule promotes competition in retail sales of contact lenses by facilitating consumers' ability to comparison shop for contact lenses. When a prescriber completes a contact lens fitting, the Rule requires that the prescriber provide the patient with a portable copy of her prescription. The Rule also requires that the prescriber verify or provide such prescriptions to authorized third parties. At the same time, the Rule requires that contact lens vendors only sell contact lenses in accordance with valid prescriptions written by licensed prescribers.

The Rule specifies that a prescriber may not require: (1) The purchase of contact lenses as a condition of providing the prescription or verification; (2) payment in addition to, or as a part of, the fee for an eye examination, fitting, and evaluation as a condition of providing the prescription or verification; or (3) the patient to sign a waiver or release as a condition of releasing or verifying the prescription.[3] The prescriber is also prohibited from requiring immediate payment before the release of a prescription, unless the prescriber requires immediate payment when an exam reveals that the consumer does not need ophthalmic goods.[4]

The Rule also places certain requirements on sellers. It mandates that sellers dispense contact lenses only in accordance with a valid prescription that is either presented to the seller or verified by direct communication with the prescriber.[5] The Rule sets out the information that must be included in a seller's verification request, and directs that a prescription is only verified under the Rule if: (1) A prescriber confirms the prescription is accurate; (2) a prescriber informs the seller that the prescription is inaccurate and provides an accurate

[1] 15 U.S.C. 7601–7610 (Pub. L. 108–164).
[2] Contact Lens Rule, 16 CFR 315 (2015).
[3] 16 CFR 315.3(b).
[4] 16 CFR 315.4.
[5] 16 CFR 315.5(a).

prescription in its stead; or (3) the prescriber fails to communicate with the seller within eight business hours after receiving a compliant verification request.[6] The Rule states that if the prescriber informs the seller within eight hours of receiving the verification request that the prescription is inaccurate, expired, or invalid, the seller shall not fill the prescription. The Rule requires that the prescriber specify the basis for the inaccuracy or invalidity of the prescription, and if the prescription is inaccurate, the prescriber must correct it.[7]

Sellers may not alter a prescription, but for private label contact lenses, may substitute identical contact lenses that the same company manufactures and sells under a different name.[8] Sellers and others involved in the manufacture, assembly, processing, and distribution of contact lenses are prohibited from representing that contact lenses may be obtained without a prescription.[9]

The Contact Lens Rule sets a minimum expiration date of one year after the issue date of a prescription with an exception based on a patient's ocular health.[10] The Rule also incorporates the Act's preemption of state and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification.[11]

B. Regulatory History

The FTC has more than three decades of regulatory and research experience regarding the optical goods industry. In addition to the Contact Lens Rule, the Commission enforces the Ophthalmic Practice Rules (hereinafter ''Eyeglass Rule''), initially promulgated in 1978.[12] Prior to the Eyeglass Rule, many prescribers either refused to release prescriptions to their patients or charged an additional fee to do so.[13] Prices for glasses varied widely, but without their prescriptions, or without paying a fee to obtain their prescriptions, consumers could not comparison shop among prescribers and other vendors and purchase from sellers that best met their needs for price, service, and convenience.[14] Moreover, competition did not lead the industry to offer what consumers could not choose: when consumers' ability to comparison shop is diminished, the normal competitive pressures on the eye care industry to offer competitive prices—or the combination of prices, features, and services most in demand—are themselves diminished. To address this problem, the Eyeglass Rule requires prescribers—generally, optometrists and ophthalmologists—to provide each of their patients, immediately after completion of an eye examination, a free copy of the patient's eyeglass prescription.[15]

Consumers, sellers, and state officials complained that contact lens consumers faced similar hurdles when trying to comparison shop for contact lenses.[16] To achieve freedom of choice and the benefits of competition for contact lens consumers, in 2003, Congress passed the Fairness to Contact Lens Consumers Act,[17] and as the Act required, in 2004, the Commission issued the Contact Lens Rule,[18] implementing the Act.

As specified in the Act, the Rule imposes requirements on both sellers and prescribers of contact lenses. Because the use of contact lenses involves significant health issues,[19] the Act requires that contact lenses be sold only to patients with valid prescriptions, which they receive after contact lens fittings. As noted above, the Act and the Contact Lens Rule only allow sales of contact lenses when the seller has a copy of the patient's prescription or has verified that prescription with the prescriber.[20] Sellers also are prohibited from altering a contact lens prescription.[21] The U.S. Food and Drug Administration (''FDA'') has strict labeling requirements for contact lenses, and it has the authority to take action against the sales of such lenses, which are medical devices, without a valid prescription.[22]

Because of concerns that many prescribers had impeded consumers' ability to comparison shop for contact lenses—even following appropriate diagnosis and fitting by the prescribers—the Act and the Rule also impose obligations on the prescribers themselves. As noted above, prescribers are required to release a copy of the prescription to the consumer, promptly upon completion of the contact lens fitting, ''[w]hether or not requested by the patient.'' [23] That copy must be complete and portable to enable comparison shopping: it must contain ''sufficient information for the complete and accurate filling of a prescription.'' [24] Prescribers also are prohibited from requiring the purchase of contact lenses as a condition of either prescription release or verification, from requiring a separate payment for prescription release or verification, and from requiring that the patient sign a waiver as a condition of prescription release or verification.[25]

Prescribers also are required to provide or verify a contact lens

[6] 16 CFR 315.5(b)–(c).

[7] 16 CFR 315.5(d).

[8] 16 CFR 315.5(e).

[9] 16 CFR 315.7.

[10] 16 CFR 315.6.

[11] 16 CFR 315.11(a). The Rule states further that ''[a]ny other state or local laws or regulations that are inconsistent with the Act or this part are preempted to the extent of the inconsistency.'' 16 CFR 315.11(b).

[12] Advertising of Ophthalmic Goods and Services, 43 FR 23992 (June 2, 1978). The Rule was revised in 1992, with the revisions codified at 16 CFR 456. Ophthalmic Practice Rules, 57 FR 18822 (May 1, 1992).

[13] 43 FR at 23998. The Commission found, for example, that in nearly every survey of practicing optometrists considered in the rulemaking record, more than 50% of optometrists imposed a restriction on the availability of eyeglass prescriptions to patients. *See id.*

[14] Fed. Tr. Comm'n, ''The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study,'' 45–46 (2005), *http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf* [hereinafter 2005 Contact Lens Report].

[15] 16 CFR 456.2 (separation of examination and dispensing). The FTC also has studied the effects of state-imposed restrictions in the optical goods industry. *See* Fed. Tr. Comm'n, Bureau of Economics Staff Paper, ''The Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry'' (1980), *https://www.ftc.gov/sites/default/files/documents/reports/effects-restrictions-advertising-and-commercial-practice-professions-case-optometry/198009optometry.pdf.*

[16] For example, in *In re Disposable Contact Lens Antitrust Litigation,* the Attorneys General of 31 states and a certified class alleged that eye care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. *In re Disposable Contact Lens Antitrust Litigation,* No. 94–MDL 1030–J–20A (M.D. Fla.). The complaints alleged two conspiracies: (1) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. *Id.* According to the complaints, the conspiracy severely restricted the supply of contact lenses available to alternative sellers, which hampered the growth of such sellers, decreased the supply of lenses to consumers, and increased the price of lenses. *Id.* The parties reached settlements, the last of which the court approved in November 2001. As part of the settlements, defendant manufacturers agreed to sell contact lenses to alternative distribution channels.

[17] 15 U.S.C. 7601–7610 (Pub. L. 108–164).

[18] Contact Lens Rule, 69 FR 40482 (July 2, 2004) (codified at 16 CFR 315). Pursuant to its congressional mandate, the FTC also issued a study of competition in the contact lens industry in 2005. *See* 2005 Contact Lens Report, *supra* note 14.

[19] *See, e.g.,* Fed. Tr. Comm'n, ''Possible Barriers to E-Commerce: Contact Lenses, A Report from the Staff of the Federal Trade Commission,'' 8–9 (Mar. 2004), *http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf* [hereinafter 2004 Possible Barriers to E-Commerce Report].

[20] 16 CFR 315.5(a).

[21] 16 CFR 315.5(e).

[22] *See* 21 U.S.C. 331(a), 333, 352(f), and 353(b)(1).

[23] 15 U.S.C. 7601(a)(1); 16 CFR 315.3(a)(1).

[24] 15 U.S.C. 7610(3); 16 CFR 315.2.

[25] 15 U.S.C. 7601(b)(1)–(3); 16 CFR 315.3(b)(1)–(3).

prescription when ''directed by any person designated to act on behalf of the patient.'' [26] Sales of contact lenses require a valid prescription that is verified by a prescriber. Such verification takes place: (1) When the prescriber confirms that the prescription is accurate, by phone, facsimile, or electronic mail; (2) when the prescriber informs the seller that the prescription is inaccurate and provides the correct prescription; or (3) when the seller seeks verification of a given prescription from a prescriber, and the prescriber does not communicate with the seller within eight business hours of the seller's request for information.[27] This eight-hour, default ''passive verification'' lessens the demands on prescribers in the event a seller forwards a query about an accurate and complete prescription from a properly identified patient. It also prevents prescribers from blocking verification—and impeding consumer access to contact lenses—simply by refusing to respond to verification requests.

C. The Evolving Contact Lens Marketplace

When contact lenses were first introduced, they were made of rigid material that required a prescriber to custom fit each pair. Beginning in the late 1980s, manufacturers began to sell disposable lenses, designed to be replaced on a daily, weekly, or monthly basis. In addition, technological advances resolved most lens-standardization issues, eliminating the need for a prescriber to fit each pair to the individual once the initial prescription had been finalized. Today, the vast majority of replacement lenses bought pursuant to an individual's prescription will be identical, regardless of whether the patient purchases them from the prescriber or a third-party seller.[28] This enables the sale of lenses to be unbundled from the fitting exam, and makes it feasible for non-prescribers to sell contact lenses.

These technological advances have increased the comfort and convenience of contact lenses, leading to growth in the number of contact lens wearers, and changes in the type and variety of lenses worn. According to the U.S. Centers for Disease Control and Prevention (''CDC''), there are now approximately 40.9 million contact lens wearers in the United States age 18 and older, representing more than 16% of the population.[29]

Overall, the U.S. market for contact lenses currently is estimated to be between $4 billion and $5 billion annually.[30] Of that, approximately 40% of sales are made by independent eye care professionals (optometrists and ophthalmologists), 19% by conventional retail chains (such as LensCrafters, etc.), 25% from mass merchants and wholesale clubs (such as Costco, Sam's Club, etc.), and 18% by online sellers (16% of sales are by ''pure play'' online sellers, such as 1–800 CONTACTS, that do not have a physical retail presence).[31] By contrast, in 2006, the total U.S. market for contact lenses was approximately $3.3 billion, with estimated online sales representing less than 13% of the market.[32]

There also are significantly more types of lenses in the U.S. now than there were 10 to 15 years ago.[33] At the same time, use of daily disposable lenses increased from just 7.5% in 2005 to 28% in 2015, while use of conventional one-year lenses declined sharply, from 19% to 1%.[34]

II. Contact Lens Rule Review

On September 3, 2015, the Commission solicited comments on the Contact Lens Rule as part of its periodic review of its rules and guides.[35] The Commission sought comments on: The economic impact of, and the continuing need for, the Rule; the benefits of the Rule to consumers purchasing contact lenses; the burdens the Rule places on entities subject to its requirements; the impact the Rule has had on the flow of information to consumers; the degree of industry compliance with the Rule; the need for any modifications to increase its benefits or reduce its burdens or to account for changes in relevant technology; and any overlap or conflict with the Rule and other federal, state, or local laws or regulations. The comment period closed on October 26, 2015.

This Notice of Proposed Rulemaking (''NPRM'') summarizes the comments received and explains the Commission's decision to retain the Contact Lens Rule. It also explains why the Commission proposes certain amendments and why it declines to propose others. Additionally, it seeks comment on certain questions. Finally, the NPRM sets forth the Commission's regulatory analyses under the Regulatory Flexibility and Paperwork Reduction Acts, as well as the text of the proposed amendments.

The Commission received 660 comments from individuals and entities representing a wide range of viewpoints, including prescribing eye care practitioners (ophthalmologists and optometrists), opticians and other eye-wear industry members, sellers of contact lenses (both online and brick-and-mortar), contact lens manufacturers, and consumer and competition advocates.[36] Virtually all commenters agreed that there is a continuing need for the Rule and that it benefits consumers and competition. The majority of commenters recommended some modifications to the Rule in order to maximize the benefits to consumers and competition, decrease the burden on businesses, protect consumers' eye health, or improve overall compliance with the Rule's existing requirements. Many commenters—including prescribers, sellers, manufacturers, legislators, and consumer advocates—also indicated that increased enforcement efforts would be beneficial.

Some commenters—including contact lens sellers, opticians, state and federal legislators, consumer advocacy groups, and others—stated that the Act's intent to provide a competitive marketplace is

[26] 15 U.S.C. 7601(a)(2) (must, as directed by authorized party, ''provide or verify'' the prescription); 16 CFR 315.3(a)(2).

[27] 15 U.S.C. 7603(d)(1)–(3); 16 CFR 315.5.

[28] However, contact lens prescriptions are brand specific, and as a general matter, one brand cannot be substituted for another, even if the other technical parameters (power, base curve, diameter, cylinder, and axis) are identical. As noted previously, sellers may substitute identical contact lenses that the same company manufactures and sells under a different name.

[29] Jennifer R. Cope et al., ''Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections—United States, 2014,'' Morb. Mortal. Wkly. Rep. 64(32):865–70, 866 (Aug. 21, 2015). *See also* Vision Council, ''Consumer Barometer,'' Sept. 2015 (estimating that 16.2% of American adults wear contact lenses).

[30] *See* Vision Council, ''Consumer Barometer,'' Mar. 2014 (valuing the U.S. contact lens market at $4.2 billion); Vision Council, ''Consumer Barometer,'' Sept. 2015 (valuing the U.S. contact lens market at $4.6 billion).

[31] Vision Council, ''U.S. Optical Industry Report Card,'' Dec. 2015.

[32] *See* Vision Council, *supra* note 30.

[33] These include, among others, soft spherical (common soft lenses), soft toric (lenses for astigmatic patients), soft multifocal (lenses for presbyotic patients), spherical corneal GP (rigid lenses for presbyotic and astigmatic patients), and scleral (lenses for patients with corneal irregularities). Furthermore, according to Johnson & Johnson Vision Care, Inc., more than 160 different brands of contact lenses are available. Comment #582. *See also* Jason J. Nichols, ''2015 Annual Report,'' Contact Lens Spectrum, Jan. 1, 2016, *http://www.clspectrum.com/articleviewer.aspx?articleID=113689*.

[34] Carla J. Mack, ''Annual Report, Contact Lenses 2007,'' Contact Lens Spectrum, Jan. 1, 2008, *http://www.clspectrum.com/articleviewer.aspx?articleID=101240*; Nichols, *supra* note 33.

[35] Contact Lens Rule, Request for Comment, 80 FR 53272 (Sept. 3, 2015).

[36] The comments are posted at: *https://www.ftc.gov/policy/public-comments/initiative-621*. The Commission has assigned each comment a number appearing after the name of the commenter and the date of submission. This notice cites comments using the last name of the individual submitter or the name of the organization, followed by the number assigned by the Commission.

not being fully realized because prescribers are not complying with one of the major underpinnings of the Rule: the automatic release of prescriptions to patients.[37] Some commenters also asserted that some prescribers are interfering with the prescription verification process and thereby impeding consumers' ability to comparison shop.[38]

Many commenters discussed the fact that the use of contact lenses presents certain eye health risks. Prescribers pointed out that merely by wearing contact lenses, patients will experience an increased risk for microbial keratitis (also referred to as infectious or bacterial keratitis).[39] Indeed, contact lens wear has been identified as the largest single risk factor for microbial keratitis.[40] Furthermore, this risk increases if a patient wears the lenses too long, wears the lenses overnight, or fails to comply with the recommended replacement schedule.[41] Other commenters noted that additional risk factors for ocular complications include improper care of the lenses or poor hygiene practices.[42] Other commenters pointed out that improperly fitting contact lenses may result in corneal ulcers and other health issues.[43]

In light of the risks associated with the use of contact lenses, many commenters—including individual prescribers, optometric and ophthalmologic associations, and contact lens manufacturers—stressed the important need to adequately protect eye health and safety and argued that the current Rule framework is not sufficient to do so.[44] For example, the Contact Lens Association of Ophthalmologists, Inc. (''CLAO'') asserted that the Rule's passive verification framework ''creates a mechanism for renewal of expired prescriptions'' and ''eliminates a critical opportunity to improve the public health of contact lens consumers by addressing risky wear and care practices.'' [45] As support, the CLAO comment cited to an article in the CDC's weekly report recommending vigorous health promotion activities to encourage contact lens wearers to improve their hygiene behaviors.[46] However, the comment did not include any empirical evidence showing that the passive verification mechanism has actually resulted in the renewal of expired prescriptions. Furthermore, the CLAO did not present any data showing that patients are not visiting their eye care practitioners as a result of the passive verification mechanism (or any other Rule provision).

Other examples of patient harm identified by commenters were either hypothetical or anecdotal (such as case reports about the experiences of individual patients).[47] The comments did not include data indicating the number or percentage of patients who obtain lenses without a valid prescription, or empirical evidence that patients are seeing their eye care practitioners less frequently than they did prior to the Rule's adoption. In addition, while some commenters stated that patients are obtaining lenses without proper medical supervision, industry data indicates that approximately 40% of contact lenses are still obtained directly from independent prescribers, and only roughly 16% of contact lenses are obtained from online-only sellers, the retail venue most frequently mentioned by commenters.[48] Most importantly, these commenters did not point to any evidence that the implementation of the Rule has increased the incidence of contact lens complications.

Other commenters argued that contact lens sales through alternative supply channels put patients at higher risk for ocular complications. The American Academy of Optometry, for example, asserted that ''careful peer reviewed research over the past ten years'' shows that ''the development of alternative supply chains for the sale of contact lenses—and the use of those alternative supply chains by contact lens patients—has itself become an identifiable risk factor for ocular morbidity in contact lens patients.'' [49] To support this contention, this commenter cited several studies that it believes show that internet purchasers of contact lenses are more likely to engage in harmful eye care practices,[50] to have a significant difference in aftercare awareness,[51] and to have a higher risk of developing microbial keratitis.[52] The Commission examined each of these studies and concludes that they are not sufficient to reliably demonstrate that purchasing lenses online is a risk factor, or that online purchasers are at a higher risk of developing microbial keratitis or any other ocular complication.[53]

[37] *See, e.g.,* Utah Retail Merchants Association (Comment #28); Information Technology & Innovation Foundation (Comment #40); Rhode Island State Representative Kennedy (Comment #536); Arizona State Representative Carter (Comment #545); Utah State Senator Bramble (Comment #576); Lens.com (Comment #614); Consumers Union (Comment #677).

[38] *See, e.g.,* LD Vision Group (Comment #544); National Association of Optometrists and Opticians (Comment #549); 1–800 CONTACTS (Comment #568); Warby Parker (Comment #593).

[39] *See, e.g.,* Whipple (Comment #15); Nelson (Comment #130). *See also* CLAO (Comment #572) (commenting that ''[t]he CDC points out that the largest single risk factor for microbial keratitis is contact lens wear''); Lupinski (Comment #499) (''[s]tudies over the years have shown that wearing contact lenses increases the risk for ocular health complications'').

[40] Cope, *supra* note 29, at 866.

[41] *See id.* at 867 (''sleeping in any type of contact lens increases risk for eye infection''); Fiona Stapleton, et al., ''The Incidence of Contact Lens-Related Microbial Keratitis in Australia,'' Ophthalmology 2008; 115:1655, 1659 (''Overnight use of [contact lenses], irrespective of material type, continues to be the main risk factor for corneal infection.''). *See also* Whipple (Comment #15); Buthod (Comment #81); Morgan (Comment #144); Lupinski (Comment #499); Bearden (Comment #554).

[42] *See, e.g.,* Shlosman (Comment #290); Israel (Comment #429); Bearden (Comment #554); Barnett (Comment #668). *See also* CLAO (Comment #572) (citing to a recent CDC report that found outbreaks of serious eye infections among contact lens wearers continue and ''are associated with failure to wear, clean, disinfect and store their lenses as directed'').

[43] *See, e.g.,* Raykovicz (Comment #35); Morgan (Comment #144); Pusz (Comment #646); *see also* American Academy of Ophthalmology (Comment #611) (''[w]earing improper lenses can further complicate existing vision issues, including leading to infection in the eye'').

[44] Commenters provided illustrations of how they believe the current operation of the Rule is jeopardizing consumer health. For example, some commenters posited that loopholes in the Rule allow patients to obtain lenses with expired, or otherwise invalid, prescriptions. According to this line of argument, patients are obtaining lenses without annual eye examinations, or without the proper medical oversight to monitor their use of contact lenses, and this could result in delayed or missed diagnosis of contact lens-related eye issues, other eye health issues, or other health conditions that otherwise would be detected during an annual eye examination. Commenters also expressed concerns that if patients do not visit eye care prescribers regularly, they will not receive proper training on the care and use of contact lenses.

[45] Comment #572. *See also* American Optometric Association (Comment #644) (''[a]llowing repurchases based on long-expired prescriptions may be, at the time, convenient for the patient and profitable for the seller, but increases the risk of patient harm'').

[46] Cope, *supra* note 29.

[47] *See, e.g.,* Combs (Comment #90) (patient with corneal ulcer had not been to doctor in eight years); Simmons (Comment #104) (patient ordered contacts using spectacle prescription with on online retailer; never given proper hygiene training); Mansito (Comment #122) (sister ordered lenses online with expired prescription; they did not fit and she needed corneal transplant); Ahn (Comment #215) (patient sleeping in lenses for a week at a time, using outdated prescription).

[48] Vision Council, ''U.S. Optical Industry Report Card,'' Dec. 2015.

[49] Comment #623.

[50] Joshua Fogel & Chaya Zidile, ''Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices,'' Optometry, 79.1 (2008) 23–35.

[51] Yvonne Wu et al., ''Contact lens user profile, attitudes and level of compliance to lens care,'' Cont. Lens Anterior Eye 33 (2010) 183–188.

[52] Stapleton, *supra* note 41.

[53] The Fogel and Wu studies have relatively small samples of consumers who purchased contact lenses over the Internet and the sample recruiting methodologies call into question whether the results are generalizable to the national population. In addition, the results of these studies link

Continued

Some commenters merely asserted that patient eye health is being compromised because online retailers do not comply with the Rule,[54] online retailer practices have convinced consumers that contact lenses are a commodity rather than a medical device,[55] and online retailers do not provide patients with proper care instructions.[56] Other prescribers alleged that patients who purchase contact lenses online or through mail order companies are noncompliant with follow-up eye care and the safe use of contact lenses,[57] or purchase lenses with expired prescriptions and then experience complications.[58] A few commenters asserted that online purchasing in particular allows patients to obtain lenses without a valid, unexpired prescription and provided anecdotal examples of patients who avoided regular eye examinations by purchasing lenses online.[59]

The Commission does not find the evidence proffered in this Rule review sufficient to support a conclusion that the Rule inadequately protects consumer eye health. Commenters did not provide sufficient reliable empirical evidence that the current Rule leads to the increased acquisition of contact lenses without a valid prescription or increased incidence of contact lens-related eye disease or adverse eye conditions. Furthermore, despite commenters' concerns about online or mail order sales of contact lenses, the Commission has not seen reliable empirical evidence to support a finding that such sales are contributing to an increased incidence, or increased risk, of contact lens-related eye problems.[60] In addition, the particular risks associated with contact lens use (or overuse) were previously considered by Congress and the Commission during the passage of the Act and the implementation of the Rule.[61] The current rulemaking record does not provide any basis to disrupt this original analysis.

III. Availability of Contact Lens Prescriptions to Patients

Section 315.3 of the Rule provides the framework under which prescribers are required to release contact lens prescriptions to patients and other authorized third parties. Section 315.3 also imposes limitations on the conditions prescribers may require of patients before releasing their prescription.

A. Section 315.3(a)(1)—Automatic Prescription Release

Section 315.3(a)(1) of the Rule requires a prescriber to provide a copy of the contact lens prescription to the patient after completing a contact lens fitting, regardless of whether it was requested by the patient. Section 315.3(a)(1) of the Rule tracks the language of the Act verbatim.[62]

This provision, referred to as automatic prescription release, was intended to empower consumers to comparison shop for contact lenses.[63] Automatic prescription release has been in effect for 12 years and is now widely supported by commenters, including both prescribers[64] and third-party sellers,[65] with several recognizing it as the ''cornerstone,''[66] or ''pillar,''[67] of the Act and the Rule. Of the 660 comments received by the Commission, none explicitly opposed the automatic release provision of the Rule although some prescribers asserted that from a safety perspective, it is in patients' best interests to purchase contact lenses from their prescribers rather than from third-party sellers.[68] More common, however, were comments supporting automatic prescription release, but suggesting that the provision was not sufficiently complied with or enforced.[69] Other commenters suggested that the automatic prescription release provision should take into account advances in technology.

1. Compliance With the Automatic Prescription Release Requirement

Several commenters stated that prescribers routinely fail to comply with the automatic prescription release requirement: Some do not—or do not always—provide a prescription unless a consumer explicitly requests it; some do not provide complete prescriptions, as required by the Rule; and some do not provide prescriptions at all.[70] These comments are, in general, concordant with complaints the Commission has received from numerous consumers apart from this rule review process.[71] Some consumer complaints, however, may be based on a misunderstanding of the Rule, as there can be confusion

purchase locations to consumer behaviors such as having a doctor check the contact lens fitting after purchase or awareness of recommended follow-up visit, rather than actual adverse eye health outcomes. The Stapleton study identified Internet/mail order purchases as a potential risk factor for microbial keratitis in a large sample from Australia. However, when the authors of the Stapleton study limit their sample to cases of moderate to severe keratitis, Internet/mail order purchases are not found to be a risk factor. *See* Fiona Stapleton et al., ''Risk factors for moderate and severe microbial keratitis in daily wear contact lens users,'' Ophthalmology 2012; 119:1516–1521.

[54] *See, e.g.,* Weissman (Comment #50); Copeland (Comment #73); Anderson (Comment #96); Woodland (Comment #98); Wheeden (Comment #214); Holliday (Comment #249); Arthur (Comment #371); Blankenship (Comment #395).

[55] Sancho (Comment #226).

[56] Miyabe (Comment #481).

[57] *See, e.g.,* Alford (Comment #18) (stating that they have a much higher rate of adverse effects such as vision threatening eye infections and inflammatory conditions, as they usually over wear their lenses and avoid seeking eye care when they have a complication).

[58] *See, e.g.,* Owen (Comment #72); Stephens (Comment #210); Ahn (Comment #215); Born (Comment #570); King (Comment #655).

[59] Gronquist (Comment #75); Buthod (Comment #81); Morgan (Comment #144); Sadeghian (Comment #242).

[60] Several commenters referenced the article published in the CDC weekly report (Cope, *supra* note 29) for the proposition that the sale of contact lenses requires stricter oversight because of this article's finding that, ''[a]pproximately 99% of wearers reported at least one contact lens hygiene risk behavior.'' The Commission notes two important caveats. First, the authors reached this number by including any wearer that indicated that they had ''ever'' engaged in a risk behavior. Hence, the 99% figure includes every wearer, who at any time, had engaged in a risk behavior even once. Second, the survey instrument asked users where they purchased their lenses, and in a separate article, the authors did not conclude that there was any difference in either habits or health risks based on whether the lenses were purchased from a provider, retail store without an exam, or over the internet. *See* Robin Chalmers et al., ''Is Purchasing Lenses from the Prescriber Associated with Better Habits Among Soft Contact Lens Wearers?,'' Cont. Lens Anterior Eye 2016 Aug 12 (Epub ahead of print) PMID: 27527924.

[61] *See, e.g.,* 2004 Possible Barriers to E-Commerce Report, *supra* note 19, at 8–12.

[62] 15 U.S.C. 7601(a)(1).

[63] Contact Lens Rule, Notice of Proposed Rulemaking, 69 FR 5440 (Feb. 4, 2004).

[64] *See, e.g.,* American Academy of Ophthalmology (Comment #611) (''we believe [the Rule] empowers consumers to comparison shop for contact lenses''); Coalition for Patient Vision Care Safety (Comment #621) (''Since enactment, and the FTC's subsequent implementation, the market for contact lenses has become extremely competitive . . . This competition has led to increased investment in research and development, and a proliferation of innovation that served to benefit the nearly 44 million Americans who use contact lenses every day.''). *See also* Carroll (Comment #5); Voight (Comment #551); Alianello (Comment #253).

[65] *See, e.g.,* 1–800 CONTACTS (Comment #568); Lens.com (Comment #614).

[66] Warby Parker (Comment #593).

[67] Rhode Island State Representative Kennedy (Comment #536); 1–800 CONTACTS (Comment #568); *see also* Utah State Senator Bramble (Comment #576); National Association of Optometrists and Opticians (Comment #549); Utah Retail Merchants Association (Comment #28).

[68] *See, e.g.,* Woo (Comment #56).

[69] *See, e.g.,* 1–800 CONTACTS (Comment #568); Lens.com (Comment #614); Utah State Senator Bramble (Comment #576).

[70] *See, e.g.,* Consumers Union (Comment #677); Rhode Island State Representative Kennedy (Comment #536); Lens.com (Comment #614).

[71] They are also consistent with longstanding practices of eye care professionals prior to enactment of the Fairness to Contact Lens Consumers Act, even in states where prescribers were required, by state statute, to release prescriptions to consumers. *See* ''Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,'' 108th Cong. 1 (Sept. 12, 2003) (Testimony of Ami Gadhia, Consumers Union).

about when or under what conditions patients should receive their prescriptions. For example, the Rule requires that a prescription be provided after the completion of the contact lens fitting, not necessarily at the conclusion of the initial visit with the prescriber. Because a fitting may not be complete until a follow-up visit, a patient might incorrectly believe that she should have been provided with her prescription at the conclusion of the first visit.

A number of prescribers commented, to the contrary, that they always provide contact lens prescriptions to their patients, and believe that others in their profession do so as well.[72] Prescribers, for their part, may be aware in a general way of their obligation to release prescriptions and yet be unaware of all of the conditions of prescription release required by the Rule. Hence, they might be mistaken in assessing, and reporting on, their own compliance.

Many reports of compliance and noncompliance are anecdotal, and robust empirical data are sparse. Although the Commission would prefer better empirical evidence about compliance and noncompliance with the Rule, and about the effects of the Rule, some survey evidence has been submitted by sellers, prescribers, and manufacturers. The Commission considers these submissions to be suggestive and, to an extent, informative, but none can be regarded as definitive. It is important to note, at the outset, that all of these surveys are subject to particular methodological limitations, as well as limits commonly associated with survey evidence. For example, patients may sometimes misremember the details of any particular prior encounter with a prescriber; prescribers, for their part, may be mistaken about the particulars of a given clinical encounter, about the frequency with which they do or do not release prescriptions, or about the frequency or severity of problems they may encounter in verifying prescriptions. For the most part, the surveys do not include independent, objective tests of patient or prescriber recollections. In addition, survey responses may be sensitive to the ways in which survey questions are framed.

As part of its comment, 1–800 CONTACTS, the country's largest online seller of contact lenses, submitted a survey conducted on its behalf by a third-party research firm, Survey Sampling International. That survey found that only 35% of contact lens wearers reported receiving a copy of their prescription without having to ask for it.[73] Another 28% reported receiving their prescription upon request (either at the office or afterwards), while 36% said they never received it at all.[74] Additional, and similarly-designed surveys, conducted on behalf of 1–800 CONTACTS in November 2014 and May 2015 found that 45% and 48% of contact lens wearers, respectively, reported that they were automatically given a hard copy of their prescription at their last eye exam.[75]

Some commenters also cited a 2008 report in a contact lens industry publication which found that just half of surveyed optometrists replied, ''yes, to every patient,'' when asked if they routinely release contact lens prescriptions.[76]

Other commenters stated that even when consumers receive a copy of their prescription, the prescription information is not always complete or correct. One online seller of replacement lenses contended that some prescribers deliberately render prescriptions incomplete by omitting information, in order to make it more difficult for consumers to buy lenses from third-party sellers.[77] According to an internal review of prescriptions on file with 1–800 CONTACTS, 23% were missing one or more parameters required to fill an order, and 43% lacked complete contact information for the prescriber.[78]

Such omissions, when they occur, may be intentional, may reflect clerical or communication errors, or may reflect an imperfect understanding of the Rule's complete requirements for prescription release. All such errors could reflect failures to comply fully with the requirements of the Rule.

The sheer number of verifications conducted by third-party sellers also may suggest that many consumers are not automatically receiving their prescriptions from prescribers, or are not receiving complete prescriptions. Under Section 315.5, verifications are only necessary if a consumer fails to provide a third-party seller with a complete prescription. According to discussions with industry, roughly three-quarters of third-party contact lens sales require prescription verification, meaning that the consumer did not present a complete prescription at the time of the attempted purchase. Seemingly contrary to this data is a survey, conducted on behalf of Johnson & Johnson Vision Care, Inc., a large contact lens manufacturer, according to which 61% of consumer respondents said that they provided the retailer with their prescription the last time they purchased lenses online or by telephone.[79] The Commission does not have enough data or insight to determine if either of these surveys accurately reflects industry practice. It is possible that some of these consumers received incomplete or otherwise problematic prescriptions. If so, those consumers might accurately report that they provided something that they believed to be a prescription at the time of purchase when, in fact, the document they provided was not complete or fillable, and hence (a) required verification and (b) was not a ''prescription'' as defined by the Rule. Alternatively, some consumers could have received their prescriptions from

[72] Howe (Comment #53). *See also, e.g.,* Galdamez (Comment #167); Ahn (Comment #215).

[73] 1–800 CONTACTS (Comment #568), Exhibit B. According to 1–800 CONTACTS, the data derives from an online survey of 500 contact lens wearers ages 18–49 years old by Survey Sampling International between Oct. 1 and Oct. 6, 2015. The respondents were not informed of the identity of the survey sponsor. The Commission has concerns about the methodology utilized for this survey, particularly about the lack of an ''I don't know'' option for various questions, but believes the information may still be suggestive, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

[74] *Id.* at 3.

[75] 1–800 CONTACTS (Comment #568), Exhibit C. According to 1–800 CONTACTS, these data are based on two surveys of 2000 contact lens wearers, randomly selected and conducted in November 2014 and May 2015. These surveys were sponsored by 1–800 CONTACTS and conducted by an independent market research company. As with the 2015 survey cited above, the Commission has concerns about the methodology utilized for these surveys but believes the information may still be suggestive, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

[76] 1–800 CONTACTS (Comment #568), Information Technology & Innovation Foundation (Comment #40), Utah Retail Merchants Association (Comment #28) *citing* Mack, *supra* note 34. Analogously, an October 2015 SurveyMonkey survey of 1,329 respondents, sponsored by online eyewear seller Warby Parker, reported that 47% of consumers who saw optometrists were not automatically provided with an eyeglass prescription at the end of the exam. Warby Parker (Comment #813 on the Ophthalmic Practice Rules), *https://www.ftc.gov/policy/public-comments/initiative-624.* The patients surveyed by SurveyMonkey were primarily consumers who purchased eyeglasses, not contact lenses, but the prescription-release requirement for eyeglass prescriptions is similar to that for contact lenses and both eyeglasses and contact lenses are prescribed by the same categories of eye care professionals. *See* Ophthalmic Practice Rules, 16 CFR 456.2.

[77] LD Vision Group (Comment #544).

[78] 1–800 CONTACTS (Comment #568) (based on a ''sample of 803 prescriptions on file with 1–800 CONTACTS.''). The Commission was not provided with the data for this sample, and so cannot judge whether the data are generalizable. Apart from this internal survey, the Commission has not received other empirical evidence demonstrating that prescribers—deliberately or otherwise—failed to provide patients with complete prescriptions.

[79] Johnson & Johnson Vision Care, Inc. (Comment #582) (August 2015 telephone survey by APCO Insight for J&J).

prescribers but misplaced them, forgot them, or simply thought it easier to obtain the refraction information from their contact lens boxes. Whatever the frequency with which each of these possibilities occurs, it is evident that third-party sellers are presently verifying a significant percentage of contact lens prescriptions with prescribers. It is also evident, based on the comments submitted, that many prescribers feel there are too many verification requests, and that it would be helpful if more patients provided a copy of their prescription to sellers rather than rely on the verification process.[80]

Another concern raised by commenters is whether consumers are even fully aware of their right to their prescriptions.[81] According to the aforementioned October 2015 survey conducted on behalf of 1–800 CONTACTS, 46% of contact lens wearers were unaware that they had a right to receive a copy of their prescription, even though the Rule has been in effect since 2004.[82] The manner in which this particular question was phrased in the 1–800 survey,[83] however, raises Commission concerns about the validity of, or the weight that should be accorded to, the results for this question. In particular, the question is leading, it lacks an ''I don't know'' option, it uses a term—''hard copy''—which some patients may not understand, and it is phrased in such a way that it could give rise to social desirability bias,[84] since respondents might be reluctant to admit that they are unaware of their rights under federal law. That being said, a response error resulting from social desirability bias in this instance would more likely lead to undercounting, or underestimation, of the number of patients who are unaware they have a right to their prescription. In other words, the way the question was phrased could make it seem that more patients are aware of their right than is actually the case, and it is thus possible that *more than* 46% of contact lens wearers are unaware that they have a right to automatically receive their prescription at the end of their contact lens fitting.

2. Commenter Suggestions for Improving Automatic Prescription Release Compliance

Some commenters asked the Commission to take specific actions to increase compliance with the automatic prescription release requirement.[85] Some commenters recommended that the Commission increase the number of enforcement actions it takes against prescribers who fail to comply with automatic prescription release in order to ''send a message to complacent prescribers.''[86] Another suggestion, put forth by 1–800 CONTACTS and other third-party sellers, is to amend the Rule to require that, immediately upon completing a contact lens fitting, prescribers provide patients with an eye care patients' ''Bill of Rights,'' informing them of their right to their prescription, that the prescription will be provided without request, and that they have a right to purchase lenses from the seller of their choice.[87] Another commenter, Consumers Union, the policy and advocacy division of Consumer Reports, suggested that prescribers inform consumers at the beginning of their visit—as part of the initial paperwork—that they will provide a prescription at the end of the examination at no additional cost.[88]

Other commenters suggested requiring patients to sign an ''Acknowledgment of Release'' document, confirming that they received their prescriptions.[89] Prescribers would be required to retain the signed acknowledgments, which then could be inspected by the Commission to verify compliance.[90] One commenter, an Arizona state representative, said she was considering introducing state legislation that would mandate such signed acknowledgments for prescribers in her state.[91]

3. Analysis of Proposals for Improving Automatic Prescription Release Compliance and Commission Proposal

Having considered the various comments and suggestions, the Commission believes that improving compliance with automatic prescription release would further the goals of the Act. While none of the five surveys[92] cited by commenters are definitive on the question of automatic release compliance, the Commission believes that the overall weight of evidence in the rulemaking record—including the surveys, the high number of verifications, the ongoing pattern of consumer complaints and anecdotal reports, and the industry's long history of failing to provide prescriptions to patients even when obligated by state law—indicates that compliance with the automatic prescription release provision could be substantially improved. Furthermore, the potential benefits of increasing the number of patients who receive their prescriptions are substantial: Increased patient flexibility and choice in shopping for contact lenses; a reduced number of verification requests, which some prescribers find burdensome; a reduced likelihood of errors associated with incomplete prescriptions; and a reduction in the number and complications of failed attempts at verification. Increasing compliance also is likely to spur more competition and innovation among contact lens sellers and manufacturers. It should also reduce the number of attempts by sellers to verify expired or inaccurate prescriptions, as well as attempts to verify prescriptions with the wrong prescriber, practices that many prescribers complained about in their comments.[93] The cumulative effect of increased compliance would likely be lower costs and improved convenience and flexibility for patients, sellers, and prescribers as well as increased accuracy of prescriptions presented to sellers, thereby reducing potential consumer harm from inaccurate, expired, or otherwise invalid prescriptions.[94]

Having determined that it would be beneficial to increase compliance with

[80] *See, e.g.,* Carroll (Comment #5) (''[Verification] is costly to my business. the patient should have a written copy of their Rx to provide to the vendor of their choice.''); Walton (Comment #543) (''It should be the consumer's responsibility to provide the seller a full, unexpired contact lens prescription and the doctor prescribing should not have to be involved in this process. It puts undue stress on small local businesses to have to respond to faxes''); Baur (Comment #170) (''If I am already handing patients a copy of their prescription, why do I have to verify the Rx at all?'').

[81] Warby Parker (Comment #593); 1–800 CONTACTS (Comment #568).

[82] 1–800 CONTACTS (Comment #568), Exhibit B.

[83] The question was phrased as follows: ''Are you aware that it is your right under federal law, as a patient to receive a hard copy of your contact lens prescription from your eye exam provider?,'' with the only possible answers being Yes or No.

[84] Social desirability bias is the tendency of survey respondents to answer questions in a manner that will be viewed favorably by others.

[85] *See, e.g.,* 1–800 CONTACTS (Comment #568); Utah Retail Merchants Association (Comment #28); Utah State Senator Bramble (Comment #576); Information Technology & Information Foundation (Comment #40); Lens.com (Comment #614); Warby Parker (Comment #593).

[86] 1–800 CONTACTS (Comment #568). *See also* Utah State Senator Bramble (Comment #576); Utah Retail Merchants Association (Comment #28).

[87] 1–800 CONTACTS (Comment #568). *See also* Warby Parker (Comment #593); Lens.com (Comment #614).

[88] Consumers Union (Comment #677).

[89] Lens.com (Comment #614); 1–800 CONTACTS (Comment #568). *See also* Arizona State Representative Carter (Comment #545).

[90] *Id.*

[91] Arizona State Representative Carter (Comment #545).

[92] *See supra* notes 73–76, citing surveys by Survey Sampling International, Contact Lens Spectrum, and SurveyMonkey.

[93] *See infra* Section IV.

[94] *See, e.g.,* Lens.com (Comment #614) (predicting that improving automatic prescription release compliance could lead to lower contact lens prices, since it would reduce verification costs for both sellers and prescribers).

the automatic prescription release provision, the Commission now evaluates various proposals put forth by commenters for how to best achieve this goal.

(a) Proposal To Increase Enforcement

Several commenters suggested that one way to better ensure automatic prescription release compliance is for the Commission to become more aggressive about enforcement.[95] According to 1–800 CONTACTS, ''Prescribers today clearly believe they can disregard their legal obligations without consequence.'' [96] 1–800 CONTACTS urged the Commission to regularly investigate prescriber practices and issue warning letters or take enforcement actions against prescribers that do not comply with the automatic prescription release provision.[97] According to 1–800 CONTACTS, this would not only change the behavior of the targeted prescribers, but would send a signal to other prescribers that they need to comply with the Rule.

The Commission recognizes the need for increased enforcement of the automatic prescription release provision and already has taken some recent steps to achieve better compliance. For example, in April 2016, the Commission sent warning letters to 45 contact lens prescribers after receiving consumer complaints alleging that the prescribers had violated the Rule, often by failing to provide patients with their prescriptions automatically.[98] The Commission acknowledges, however, that the absence of documentation makes it difficult to determine whether a prescriber did or did not provide a patient with a prescription as required, in any particular case. The absence of documentation also makes it difficult to determine how many times, or how frequently, a noncompliant party has violated the Rule. Instead, allegations and denials of Rule violations might often become a matter of the patient's word against that of the prescriber, making accurate enforcement decisions, as well as enforcement actions predicated on those decisions (as opposed to warning letters) more challenging. The Commission thus believes that enforcement could improve through a mechanism to increase its ability to assess and verify compliance with the Rule's automatic prescription release requirements.

(b) Proposal To Require an Eye Care Patients' Bill of Rights or Notice-Upon-Check-In

A number of commenters recommended that the Commission amend the Rule to require that prescribers provide patients with written notices informing them of their right to their prescription. One suggestion, proposed by three online sellers of eye wear, is that, immediately upon completion of a contact lens fitting, prescribers provide patients with a ''Bill of Rights''; that is, a written notice informing patients of their rights under the Rule, including: (1) The right to receive their prescriptions; (a) provided promptly and automatically without their having to request them; (b) at no additional charge; and (2) the right to purchase their lenses from the seller of their choice.[99] Another suggestion, put forth by a consumers' rights organization, is that the Rule require that, ''the eye doctor inform the consumer at the beginning of the visit, as part of the initial paperwork, that the prescription will be provided at the conclusion of the visit at no additional cost.'' [100]

Either of these proposals, if implemented and complied with, would notify consumers of their rights and, presumably, would increase the percentage of patients who receive prescriptions from their prescribers. Providing the required document would remind prescribers and their staffs to provide patients with their prescriptions, and it would remind patients to ask for their prescriptions in the event that the prescriber might fail to provide them initially and without a request, as the Rule and the Act already require.

Since the Commission could draft the specific language for either the ''Bill of Rights'' or check-in notice, it could ensure that the notice conveys an accurate explanation of the Rule's automatic prescription release requirements, something prescribers sometimes fail to do.[101] The requirement should also impose a relatively small burden upon prescribers, since prescribers would only need to provide a brief, standard form for each patient.

On the other hand, patients already receive forms and other paperwork when they visit a prescriber, increasing the possibility that patients might not read or attend to the information in the ''Bill of Rights'' or check-in notice.

Moreover, the Rule already requires that prescribers provide patients with copies of their prescriptions, yet diverse complaints have alleged that many prescribers do not do so. It is at least possible that many prescribers who now fail to comply with the Rule's prescription release requirements would also fail to comply with a requirement to provide a patients' ''Bill of Rights'' or check-in notice form. Without some mechanism to ensure compliance, a notice by itself might not provide substantial benefits. The notices recommended by these proposals would not require the type of prescriber record-keeping needed to assist the Commission in better Rule enforcement, either in its current form or as it might be amended. It is thus possible that adding this requirement would impose an increased burden on prescribers without providing many tangible, countervailing benefits to consumers. In light of these considerations, the Commission has determined not to propose to amend the Rule to require either a Bill of Rights or notice-upon-check-in.

(c) Proposal To Require a Signed Acknowledgment Form

Another amendment recommended by some commenters is to require that prescribers present, and patients sign, an ''acknowledgment of release,'' confirming that they received their prescription at the end of their contact lens fitting.[102] Such an acknowledgment would be a separate, stand-alone document, and prescribers would be required to retain the signed acknowledgments.[103]

An acknowledgment of release would notify consumers of their prescription portability rights and, in all likelihood, increase the percentage of patients who receive their prescription from the prescriber. Providing the required form would also serve as a reminder to

[95] 1–800 CONTACTS (Comment #568). *See also* Utah State Senator Bramble (Comment #576); Utah Retail Merchants Association (Comment #28).

[96] 1–800 CONTACTS (Comment #568).

[97] *Id.* at 25–26.

[98] Press Release, Fed.Tr. Comm'n, FTC Issues Warning Letters Regarding the Agency's Contact Lens Rule (Apr. 7, 2016), *https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule.*

[99] 1–800 CONTACTS (Comment #568). *See also* Warby Parker (Comment #593); Lens.com (Comment #614).

[100] Consumers Union (Comment #677).

[101] Imprecise word selection by prescribers may, in some cases, lead prescribers to inadvertently violate the rule. For example, an eye care practitioner may believe he is complying by asking patients, ''Do you want a copy of your prescription?'' when, in fact, such a question is a violation of the automatic release provision since the prescription is not provided automatically but rather requires patients to confirm that they want it. This, in turn, may put patients in an awkward position since they may feel they are going behind the prescriber's back by shopping for contacts elsewhere.

[102] Lens.com (Comment #614); 1–800 CONTACTS (Comment #568). *See also* Arizona State Representative Carter (Comment #545).

[103] *Id.*

prescribers and their staffs to provide patients with their prescriptions, and serve as a reminder to patients to ask for their prescription in the event that they receive the acknowledgment form but not the prescription. Once it becomes an established practice, an acknowledgment form might also reduce confusion for patients as to when their contact lens fitting is actually complete, thus reducing the likelihood of erroneous complaints about a prescriber's perceived failure to provide a prescription after the completion of a preliminary examination but when the contact lens fitting has not yet been completed.

Additionally, since patients would have to affirmatively sign such an acknowledgment, it is less likely that such a document would go unnoticed or unread by patients than a ''Bill of Rights'' or notice-upon-check-in type of document. And perhaps most importantly, requiring prescribers to retain a signed acknowledgment form would improve the Commission's ability to verify whether prescribers had complied with this requirement and had met their obligation to release prescriptions to their patients. Being able to determine more accurately whether a particular prescriber had provided a prescription in a particular case would reduce the number of instances where a filed complaint simply pits the patient's word against that of the prescriber. It would also enable the Commission to evaluate the overall rate at which both individual prescribers and the population of prescribers comply with the requirement.

One potential drawback to requiring a signed acknowledgment requirement is the increased recordkeeping burden imposed on prescribers, since they would have to provide the forms and retain the signed acknowledgments for a certain period of time.[104] This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and input automatically into the electronic record. Furthermore, prescribers also could scan signed paper copies of the acknowledgment form and store those forms electronically to lower the costs of this recordkeeping requirement. Accordingly, the Commission believes that any recordkeeping burden would be relatively minimal and outweighed by the benefit of having more patients in possession of their prescriptions.

(d) Proposal To Require Signage

Another possible Rule revision is to require that prescribers' offices post conspicuous signage informing consumers of their right to their prescription. Although this was not specifically suggested by commenters,[105] it is currently required by law in California, and the practice could be expanded via the Rule to apply nationwide.

In California, the Business and Professional Code provides that each prescriber office must post, in a conspicuous place, a notice informing patients that eye doctors are required to provide patients with a copy of their ophthalmic lens prescriptions. The notice also explains that spectacle prescriptions are released upon the completion of the exam, and contact lens prescriptions are released upon the completion of the exam or upon the completion of the fitting process.[106]

Such a requirement, if adopted in the Rule, could provide some of the same benefits of the Bill of Rights, notice-upon-check-in, and signed acknowledgment proposals in that it would, in theory, notify consumers of their rights and, presumably, increase the percentage of patients who receive their prescription from the prescriber. A sign could also serve as a reminder to patients to ask for their prescription in the event the prescriber does not provide it. Furthermore, a sign would impose less of a burden on prescribers than the other proposals, since it would only have to be posted once, as opposed to individual copies for each and every patient. Lastly, enforcing such a provision would be relatively straightforward, since the Commission could perform spot checks on prescribers' offices to ensure they have posted the required signage.

On the other hand, the Commission lacks good evidence about the effects of California's particular version of this requirement, and it is unclear how many patients actually read posted notices at doctors' offices, particularly in locations where there are already numerous ads or other postings about various rights, requirements, and obligations. It is likely that far fewer patients would learn of their rights from a single sign—competing for attention with ads and other signage—than from being handed or shown a document, particularly a document consumers are required to sign. Moreover, since a sign would not require a prescriber to interact with each patient, it would serve as less of a reminder to prescribers and their staff to provide patients with their prescriptions. And, although it would be relatively straightforward for the Commission to verify and enforce the signage requirement, such a requirement would do little to assist the Commission in verifying or enforcing compliance with the automatic prescription release provision itself. Furthermore, Commission staff would have to physically visit prescribers' offices located throughout the country to verify the signage, resulting in the expenditure of more Commission resources to monitor compliance.

(e) The Commission's Proposal To Require a Signed Acknowledgment

After consideration of the comments and proposals, the Commission proposes to add a signed acknowledgment requirement. The Commission believes such a provision will help inform patients of their right to their prescriptions, increase the number of patients who receive their prescriptions and, consequently, increase the number of purchases made with initial presentations of complete and valid prescriptions, thus reducing the number of verifications by third-party sellers. The addition of a signed acknowledgment requirement accomplishes the desired objectives with little increased burden on prescribers. The Commission believes that implementation of signed acknowledgments would best serve several important objectives: Reminding prescribers to release prescriptions, informing patients of their rights, reducing misunderstandings, and improving the Commission's verification and enforcement ability.

The requirement that the prescriber request the patient acknowledge receipt of the contact lens prescription is triggered once the prescriber has presented the prescription to the patient. The patient shall receive the prescription prior to being asked to sign the acknowledgment form, and signing the acknowledgment form is not a condition to obtain the prescription. If the patient refuses to sign or cannot sign the acknowledgment form, the prescriber must note the refusal or

[104] 1–800 CONTACTS suggested that prescribers should maintain records of acknowledgments for three years or the length of the prescription, whichever is longer. 1–800 CONTACTS (Comment #568).

[105] It was cited in the National Association of Optometrists and Opticians comment, but not expressly recommended. Comment #549.

[106] 16 CCR § 1566. California also has an additional state law, CAL Bus. & Prof. Code § 2554, which essentially requires the same signage, with the addition of a notice stating, ''Patients may take their prescription to any eye doctor or registered dispensing optician to be filled,'' and requiring the inclusion of complaint contact information for the California Board of Optometry.

inability on the acknowledgment form and must maintain the form.

The acknowledgment form may be either paper or in electronic format. The acknowledgment form, whether paper or electronic, must be entitled ''Patient Receipt of Contact Lens Prescription,'' and must state, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice.'' The acknowledgment form shall be in a format that allows either conventional or electronic signatures. Prescribers may maintain copies of the acknowledgment forms in paper or electronically.

The Commission, therefore, proposes to amend Section 315.3 to add the requirement that upon completion of a contact lens fitting, and after providing a copy of the contact lens prescription to the patient, the prescriber shall request that the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form entitled, ''Patient Receipt of Contact Lens Prescription.'' This form must state, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand I am free to purchase contact lenses from the seller of my choice.'' In addition, the form must also include the name of the patient, the patient signature, and the date the form was signed. In the event that the patient declines to sign the acknowledgment form, the prescriber shall note the patient's refusal on the form and sign it. No other statements or information, other than the address or letterhead of the prescriber, shall be placed on the acknowledgment form.

The Commission also proposes to amend Section 315.3 to add the requirement that prescribers maintain the signed acknowledgments for a period of not less than three years, so that the signed acknowledgments are available for inspection by the Federal Trade Commission. The full text of the proposed Rule amendment is located in Section X of this notice.

4. Additional Mechanisms for Improving Prescription Portability

The increasing number of prescribers who offer patient ''portals'' accessible via the Internet has made it possible for prescribers to post, and patients to obtain, prescriptions online, while maintaining the security and privacy of patients' health information.[107] This, along with the patient's ability to email prescription copies to sellers, increases prescription portability. It also could reduce the verification burden on prescribers, to the extent that patients could quickly and reliably obtain complete and accurate copies of their prescriptions,[108] without making specific requests to their prescribers for such copies, and to the extent that such prescriptions could be filled without the seller intervening to verify the prescriptions directly with the prescribers. In addition, patient portals do not raise the same concerns expressed by some prescribers about sharing patient prescription information with third parties, because patient portals enable the secure sharing of such information directly with the patients themselves.[109]

Accordingly, the Commission believes that the use of patient portals to provide patients with access to electronic copies of their prescriptions can benefit prescribers, sellers, and patients. The Commission encourages prescribers, in addition to providing patients with a copy of their prescriptions, to make prescriptions available via patient portals in accordance with federal and state law, including HHS guidance. Uploading prescriptions to patient portals will make it easier for patients to access their prescriptions and, consequently, to transmit them to sellers when purchasing lenses. This, in turn, may substantially increase the accuracy of seller-filled orders and reduce the verification burden on prescribers.[110] To facilitate the likelihood that patient portals will increase prescription portability, the patient portal should be configured to allow the patient to download, save, and print the prescription, as well as to allow the patient to email, or otherwise transmit, prescriptions directly to a seller.

At this time, the Commission does not have enough information to determine whether solely posting a contact lens prescription to a patient portal is sufficient to satisfy the Rule's obligation for prescribers to provide copies of contact lens prescriptions to patients. However, the Commission seeks comment on the use and adoption of patient portals, as well as the potential ability for such technology to allow prescribers to comply with the automatic prescription release requirement of the Rule.

B. Section 315.3(a)(1)—Additional Copies of Prescriptions

Some commenters requested that the Commission amend the Rule to expressly obligate prescribers to provide duplicate prescription copies to patients upon request.[111] According to Consumers Union, such a requirement would provide ''additional protection for situations in which the eye doctor neglects to provide the prescription during the visit, as well as for situations in which the prescription is misplaced by the consumer.'' [112] Likewise, the health and safety organization Prevent Blindness asserted that duplicate copies should be available upon request since ''[i]t is a basic consumer right to own one's prescriptions.'' [113]

During the initial rulemaking, the Commission stated that the Act neither requires prescribers to release, nor prohibits them from releasing, additional copies of the prescription.[114] At that time, the Commission declined

[107] Although the Commission lacks data on the use of patient portals by ophthalmologists or optometrists in particular, the Commission notes that a recent report to Congress observes that increasing numbers of physicians and other types of health care providers are sharing information electronically with their patients. For example, in 2014, four in 10 office-based physicians reported sharing information electronically with their patients, and 57% of all physicians reported sharing information directly with their patients electronically. U.S. Dep't Health & Human Servs., Office of the National Coordinator for Health Information Technology, Report to Congress, ''Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information'' 28–30 (2016), *https://www.healthit.gov/sites/default/files/Attachment_1_-_2-26-16_RTC_Health_IT_Progress.pdf.*

[108] Empirical studies of the integrity of electronic transmission of prescription information chiefly focus on systems for transmitting prescription drug information and not contact lens prescriptions. Still, such studies suggest that the adoption of electronic prescribing greatly reduces the error rate associated with handwritten paper prescriptions. *See, e.g.,* Rainu Kaushal et al., ''Electronic Prescribing Improves Medication Safety in Community-Based Office Practices,'' 25 J. Gen. Intern. Med. 530, 530 (2010) (finding that, ''For e-prescribing adopters, error rates decreased nearly sevenfold, from 42.5 per 100 prescriptions (95% confidence interval (''CI''), 36.7–49.3) at baseline to 6.6 per 100 prescriptions (95% CI, 5.1–8.3) one year after adoption (p<0.001). For non-adopters, error rates remained high at 37.3 per 100 prescriptions.'').

[109] *See, e.g.,* U.S. Dep't Health & Human Servs., HealthIT.gov, ''Do I Need to Obtain Consent From My Patients to Implement a Patient Portal?,'' *https://www.healthit.gov/providers-professionals/faqs/do-i-need-obtain-consent-my-patients-implement-patient-portal* (noting that HIPAA permits the disclosure of health information to the patient without requiring the patient's express consent and that portals are ''an excellent way to afford patients access to their own information and to encourage them to be active partners in their health care.'')

[110] *See* Kaushal, *supra* note 108.

[111] Prevent Blindness (Comment #13); Consumers Union (Comment #677).

[112] Consumers Union (Comment #677).

[113] Prevent Blindness (Comment #13).

[114] 69 FR at 40492.

to require or prohibit the release of additional copies of the prescription.[115]

Upon consideration of the comments, the rulemaking record, and a re-examination of the language of the Act itself, the Commission now clarifies that the Act and the Rule require that prescribers provide patients with additional copies of their prescriptions upon request. Accordingly, the Commission believes there is no need to amend the Rule, but seeks comment on this clarification.

This determination is supported by a number of considerations. First, as noted above, during the initial rulemaking, the Commission stated that the Act neither requires nor prohibits additional copies of the prescription. However, this statement was made in response to two commenters who recommended that the prescription release obligation be *limited* to one release per patient. Thus, the Commission did not fully consider whether additional copies should be required, only that the Act did not expressly limit patients to one copy.

Second, the Act and the Rule require that prescribers provide or verify the patient's prescription when so ''directed by any person designated to act on behalf of the patient.'' [116] This provision has been interpreted to mean that prescribers must provide a prescription whenever a patient authorizes an agent to request one, even if the patient previously received a prescription copy from the prescriber.[117] The Commission's Division of Advertising Practices, which administers and enforces the Rule, arrived at this interpretation based upon the plain language of the Act and Rule, as well as upon recognition that when consumers want to order contact lenses, ''some consumers have neither their prescription nor sufficient information about their prescription for [the seller] to prepare a proper verification request.'' [118] Based upon this interpretation, duly authorized patients' agents (sellers) are able to obtain a duplicate copy of the patients' prescription upon request. In addition, patients, acting as their own agents, are able to obtain a duplicate copy of their prescription upon request.[119]

Furthermore, as discussed earlier, because the Commission believes that many prescribers are not providing patients with their prescriptions upon completion of their contact lens fitting,[120] there is additional justification for ensuring that patients are able to obtain copies of their prescription when necessary. The Commission therefore believes that requiring prescribers to provide additional copies of contact lens prescriptions to patients upon request is consistent with the language and intent of the Act: Providing prescription portability while protecting consumer health. Consumers with ongoing access to their prescriptions will be able to obtain the correct contact lenses from the seller of their choosing.

C. Section 315.3(a)(2)—Provide or Verify the Contact Lens Prescription

Section 315.3(a)(2) of the Rule requires that prescribers shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.[121]

1. Sellers Designated To Act on Behalf of Patients

In addition to the obligation to release the prescription to the patient at the completion of a contact lens fitting, the Rule also requires prescribers to provide the contact lens prescription to third parties acting on behalf of the patient.[122] Accordingly, some sellers, at the direction of their customers, have requested copies of prescriptions from prescribers rather than just verifications of prescriptions.[123]

Because this practice historically has been a source of confusion for some eye care practitioners, the staff clarified, in a 2006 letter to the American Optometric Association, that the Rule obligates a prescriber to provide the consumer's complete prescription to a third-party seller if the consumer has authorized that seller as an agent.[124] In its letter, FTC staff also made clear that the Act and the Rule do not permit the prescriber to require that sellers provide written documentation of the patient's authorization before providing the seller with a copy of the patient's prescription.[125] In response, the American Optometric Association has provided guidance to its members that they must comply with this provision of the Rule.[126]

This option may be gaining popularity with at least one seller. As explained by 1–800 CONTACTS, ''[d]ue in large part to poor prescriber compliance with prescription release requirements, many customers cannot provide a third-party seller with [a] copy of their contact lens prescription at the time they place their order.'' [127] 1–800 CONTACTS also pointed out that this option benefits consumers because with a copy of the prescription on file, it can ship orders without any delay and without having to contact the prescriber each time the consumer wishes to purchase lenses.[128]

In its comment, however, the American Optometric Association argued that ''[r]equests by sellers directly to physicians for copies of patient prescriptions should be disfavored.'' [129] The American Optometric Association asserted that sellers should use the verification system instead because verification requests consume less time than the retrieval, copying, and transmission of the actual prescription to sellers. The American Optometric Association acknowledged that it believes that the Rule's verification system needs improvement, but pointed out that it contains safeguards that requests for

[115] *Id.*

[116] 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2).

[117] *See* Staff Opinion Letter to the American Optometric Association Providing Guidance Regarding How Contact Lens Prescribers Should Respond to Requests for Patients' Contact Lens Prescriptions, Pursuant to the Fairness to Contact Lens Consumers Act and the Contact Lens Rule, Oct. 4, 2006 (stating that if the seller is an agent of the consumer, ''the prescriber has an obligation under the FCLCA and the Contact Lens Rule to provide the consumer's prescription'' to the seller) *https://www.ftc.gov/public-statements/2006/10/requests-contact-lens-prescribers-provide-patients-contact-lens*; 1–800 CONTACTS (Comment #568), Exhibit E (same).

[118] *Id.* The American Optometric Association takes exception to this interpretation, and argues that if Congress meant for retailers to be able to demand patients' prescription at any time, then ''the entire verification process would have been all but unnecessary.'' Comment #644. The Commission disagrees with this contention, however, because verification is simply an additional option for ensuring that patients have a valid prescription, one that is faster and less paper-intensive, for both the seller and prescriber, than requiring that the prescriber always provide the complete patient prescription. Moreover, the Act and the Rule state that the prescriber must provide or verify the contact lens prescription as directed by the patient's agent, thus leaving it up to the agent, if so authorized by the patient, to decide which method is preferable.

[119] 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2). In addition, the HIPAA Privacy Rule right of access requires a covered prescriber to provide a copy of a prescription to the patient upon request or to another person she designates. *See* 45 CFR 164.524(c)(3). *See infra* Section V.C.

[120] *See supra* Section III.A.1.

[121] 16 CFR 315.3(a)(2).

[122] *Id.*

[123] *See, e.g.,* 1–800 CONTACTS (Comment #568).

[124] Staff Opinion Letter, *supra* note 116.

[125] The opinion letter also explains that neither the Health Insurance Portability and Accountability Act (''HIPAA'') of 1996 nor its implementing regulations require such written documentation of the authorization.

[126] American Optometric Association, Summary of Advisory from AOA General Counsel Regarding FCLCA Enforcement Update, Sept. 1, 2015, *http://www.aoa.org/Documents/advocacy/FTC_guidance_on_Rx_releases.pdf.*

[127] Comment #568.

[128] *Id.*

[129] Comment #644.

copies of prescriptions do not.[130] The American Optometric Association stated that sellers would only need to request a copy of a prescription directly from the prescriber when the patient does not submit the prescription and the patient is unable to provide any information about the prescription to the seller in order to permit use of the verification process.[131]

Few other prescribers addressed this issue directly in their comments to this Rule review.[132] However, the Commission also has received anecdotal reports that prescribers are still confused about this provision of the Rule, and some comments appear to conflate requests for a copy of a prescription with an incomplete verification request. For example, some prescribers complained that 1–800 CONTACTS was sending them incomplete verification requests, but instead it appears that 1–800 CONTACTS was sending the prescriber a request for the patient's prescription.

The Commission declines to adopt the American Optometric Association's suggestion that requests for copies of a prescription by a duly authorized seller be discouraged. The plain language of the Act and the Rule provide for this method of acquiring a prescription and the Association provided no evidence demonstrating that providing a copy of a prescription to a seller, rather than verifying a prescription, was significantly more burdensome to prescribers. As to the contention that the verification system contains safeguards that requests for prescriptions do not, the Commission points out that a prescription provided by a prescriber directly to the seller would necessarily include all relevant information and would avoid some of the issues raised by commenters about the flaws of the verification system. In addition, the copy of the prescription provided by the prescriber to the seller would contain an expiration date, which also serves as a safeguard against the improper dispensing of contact lenses.

Despite clarifications that prescribers must provide copies of prescriptions to sellers when authorized by the patient, 1–800 CONTACTS complained in its comment that in its experience, about half of prescribers ''routinely ignore [their] requests'' for a copy of a patient's prescription.[133] To address problems encountered by authorized agents in procuring copies of prescriptions, as well as ongoing prescriber confusion about this provision, two commenters proposed amending Section 315.3 ''to require that in response to an authorized request, the prescriber send the prescription to the agent (by mail, facsimile or a digital image of the prescription that is sent via electronic mail) within eight business hours as currently defined under the [Rule].'' [134]

In support of its proposal, 1–800 CONTACTS stated that, ''[e]vidence shows that in about half the cases, prescribers ignore and never respond to 1–800's authorized requests for a copy of a customer's prescription.'' [135] 1–800 CONTACTS does not specify this evidence in its comment. However, in a 2006 letter to the Commission, 1–800 CONTACTS asserted that an audit of 264 requests for a copy of a customer's prescription shows that 46% of prescribers did not respond within five business days.[136] The other commenter, Warby Parker, provided no evidence in support of its proposal.[137]

The Act and the Rule currently require the prescriber to provide a copy of a prescription to an authorized third party, but is silent on the timing of the response. The proposed modification would require prescribers to provide a prescription within eight business hours, the same amount of time that prescribers are afforded to respond to a verification request. The Commission notes, however, that there is a qualitative difference between responding to a verification request as opposed to providing a copy of a prescription. First, if the verification request is correct, the prescriber need take no action.[138] Second, the proposed modification would require the prescriber to act within eight business hours, and if the prescriber did not act, or was unable to act, she would be in violation of the Rule. The eight-business-hour window for verification does not place the prescriber in such jeopardy. If the prescriber is unable to respond to a verification request in a timely fashion—for whatever reason—the request is verified, but the prescriber is not in violation of the Rule.

At this time, the Commission has determined that the existing rulemaking record is not sufficient to support a Rule modification requiring a prescriber to respond to a request for a copy of a prescription within eight business hours. Accordingly, the Commission requests additional information from commenters on the costs and benefits of imposing a timeframe for prescribers to respond to requests from authorized third parties for a copy of a patient's prescription. The Commission also seeks comment on the appropriate amount of time for a prescriber to respond to prescription requests.[139]

IV. Prescriber Verification

Section 315.5 of the Rule provides the framework under which sellers may dispense contact lenses to consumers and requires sellers, before selling contact lenses, to either obtain a copy of the patient's prescription or verify the prescription. Section 315.5 also sets forth the procedures for obtaining such verification as well as seller recordkeeping obligations.

A. Section 315.5(a)—Prescription Requirement

Section 315.5(a) of the Rule provides that a seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is presented to the seller by the patient or prescriber directly or by facsimile; or verified by direct communication. This provision was taken verbatim from the Act.[140]

1. Presentation of Prescriptions ''Directly or by Facsimile''

In the initial rulemaking, the Commission determined that the ''directly or by facsimile'' language of section 4(a)(1) of the Act allowed the

[130] Although the American Optometric Association comment did not specifically mention the safeguards, it is likely that the comment is referring to fact that if a prescription verification request lists a quantity of lenses that is excessive, the prescriber can deem such a request ''inaccurate.''

[131] Comment #644.

[132] Diener (Comment #6) (the ''rule should be restricted to use only upon recent patient request, not used in perpetuity to obtain records for marketing purposes''); Vidulich (Comment #612) (silent on the issue, but attaching request for a copy of the prescription).

[133] Comment #568.

[134] *Id.; see also* Warby Parker (Comment #593).

[135] Comment #568.

[136] *See* 1–800 CONTACTS (Comment #568), Exhibit E.

[137] Warby Parker (Comment #593). Warby Parker also proposed that the prescriber be required to maintain a log recording the date and time a patient's prescription was requested and released to the authorized agent.

[138] Based on discussions with industry, it appears that the vast majority of verification requests are passively verified, with no prescriber action taken.

[139] Another commenter, Opternative, a telehealth provider, proposed that the Commission ''consider expanding the verification requirements so that prescribers' obligations also apply to any other third party, including other prescribers, that is authorized by the patient.'' Comment #648. Section 315.3 explicitly states that the prescriber shall provide or verify the contact lens prescription, ''as directed by any person designated to act on behalf of the patient.'' Nothing in the Act or Rule precludes the construction of ''any person'' from including other prescribers. Furthermore, the HIPAA Privacy Rule permits a ''covered entity'' to use or disclose protected health information without patient authorization ''for treatment, payment, or health care operations.'' 45 CFR 164.506. The Commission does not believe that the Rule needs any modification on this issue.

[140] 69 FR at 40495; *see also* 5 U.S.C. 7603(a).

patient or prescriber to present a prescription by mail, by facsimile, or through a digital image of the prescription that is sent via electronic mail.[141] The Commission also decided at that time not to include ''substantially equivalent future technologies'' within the scope of acceptable direct presentation mechanisms.[142] In doing so, the Commission noted that section 4(a)(1) of the Act did not expressly reference or contemplate future technologies and the Commission was not aware of other technologies that met the statutory standard. The Commission declined at that time to include future technologies that ''do not involve an exact copy of the prescription within the scope of acceptable direct presentation mechanisms.'' [143]

Since implementation of the Rule in 2004, technological advances—including many spurred by federal and state health information technology initiatives [144]—have fostered the proliferation of patient portals, through which health care providers can securely share medical information, such as prescription information, directly with patients and certain third parties. The use of patient portals for presentation of contact lens prescriptions to sellers may provide many benefits to consumers and competition. When using a portal, the patient or prescriber will have direct access to a current, exact copy of the contact lens prescription, reducing the chance that an inaccurate or expired prescription might be presented to the seller. The use of patient portals may also reduce costs for prescribers, patients, and sellers by making it easier and more efficient for patients to share and present contact lens prescriptions, and by reducing the number of verification requests placed on prescribers.

Because of these potential benefits, the Commission has made an initial determination that the provision ''directly or by facsimile'' includes the use of online patient portals by patients and prescribers to present contact lens prescriptions to sellers. In doing so, the Commission notes that the use of a patient portal necessarily involves ''an exact copy of the prescription within the scope of acceptable direct presentation mechanisms.'' [145] The Commission seeks comment on this clarification and requests that commenters provide information about whether the Commission should consider any other issues related to the presentation of prescriptions to sellers.

2. ''Verified by Direct Communication''

Some individual commenters recommended that the Commission revise the Rule to remove verification by direct communication, and argued that the sale of contact lenses should be conditioned upon presentation of a written prescription by the consumer to the seller. These commenters noted that consumers are already being provided with a written prescription as required by the Rule, and that requiring prescribers to verify prescriptions with the seller as well was redundant, time-consuming and burdensome.[146] Other commenters noted that with electronic means such as email and phone cameras readily available, the consumer should be responsible for presenting the prescription to the seller rather than having the prescriber verify the prescription.[147] Other commenters argued that contact lens prescriptions should be treated the same way as prescriptions for medications, and that consumers should only be able to obtain contact lenses by presenting a written prescription.[148] Some commenters also stated that relying on a written prescription to dispense lenses, rather than prescriber verification, would close loopholes in the verification framework that may allow consumers to obtain lenses without a valid, unexpired prescription.[149]

The language of Section 315.5(a)(2) was taken verbatim from the Act.[150] Because Congress decided to structure the prescription verification framework to allow for either the direct presentation of a prescription to a seller or, alternatively, the verification of a prescription by direct communication, elimination of verification by direct communication is beyond the scope of this rule review.

3. Automated Telephone Calls as a Method of Direct Communication

The Commission received numerous comments objecting to contact lens sellers' use of automated telephone calls as a method to communicate verification requests.[151] These commenters, who often refer to these automated telephone calls as robocalls, are largely prescribers, students of optometry, and associations whose members are prescribers.

Commenters described problems arising from the use of automated telephone calls,[152] and some

[141] 69 FR at 40495. The Commission also concluded that presentation of the prescription information from the consumer to the seller by telephone or by email (other than an email containing a digital image of the prescription) did not meet the ''directly or by facsimile'' standard imposed by the Act.

[142] *Id.*

[143] *Id.*

[144] Numerous federal and state programs have been designed to foster the development of health information technology and the electronic processing, storage, and transmission of patients' health information. For example, under the HITECH Act of 2009—Title XIII and Title IV of Division B of the American Recovery and Reinvestment Act of 2009—Congress directed the Medicare and Medicaid programs to make direct payments to eligible healthcare professionals, hospitals, and certain other healthcare providers specifically to incentivize the adoption and meaningful use of electronic health records systems (EHRs). American Recovery and Reinvestment Act of 2009 (Recovery Act), Public Law 111–5, § 4101(a), 4101(b), and 4202 (2009) (Medicare incentives for eligible professionals, Medicare incentives for hospitals, and Medicaid provider payments, respectively). According to a recent report by the U.S. Department of Health & Human Services, more than $30 billion in such incentive payments were made between 2011 and 2015. U.S. Dep't Health & Human Servs., Office of the National Coordinator for Health Information Technology, Report to Congress, ''Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information'' 18 (2016), *https://www.healthit.gov/sites/default/files/Attachment_1_-_2-26-16_RTC_Health_IT_Progress.pdf.* Regarding patient portals in particular, *see, e.g.,* U.S. Dep't Health & Human Servs., Office of the National Coordinator for Health Information Technology, ''ONC Patient Engagement Playbook,'' *https://www.healthit.gov/playbook/pe/introduction/.*

[145] 69 FR at 40495.

[146] Carroll (Comment #5), Driscoll (Comment #67); Kirk (Comment #131); Kalman (Comment #150); Baur (Comment #170); Bricker (Comment #195); Ahn (Comment #215); Comer (Comment #221); Kubo (Comment #234); Sanders (Comment #235); Williston (Comment #252); Campbell (Comment #348); Falcon (Comment #505); Walton (Comment #543).

[147] Kiener (Comment #74); Kubo (Comment #234); McWilliams (Comment #362); Falcon (Comment #505); Pham (Comment #641).

[148] Driscoll (Comment #67); Moody (Comment #92); Filandro (Comment #129); Kirk (Comment #131); Kalman (Comment #150); Boyer (Comment #246); Bolenbaker (Comment #357).

[149] Driscoll (Comment #67); Dieckow (Comment #151); Ahn (Comment #215); Sanders (Comment #235); Smith (Comment #319).

[150] 69 FR at 40495; *see also* 5 U.S.C. 7603(a).

[151] The American Optometric Association pointed to the public's general disfavor of robocalls, noting that they are commonly understood to be an abuse of telephone communication, one for which companies have been fined millions of dollars. Comment #644. The FTC disagrees with this characterization of automated seller verification calls. Contact lens seller verification calls are not sales calls covered by the Telemarketing Sales Rule (''TSR''), 16 CFR 310, which prohibits certain robocalls. In addition, the TSR does not apply to most business-to-business communications. 16 CFR 310.6(b)(7).

[152] *E.g.,* Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Borsky (Comment #26); Matthews (Comment #25); Maanum (Comment #23); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Virginia Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Howe (Comment #53); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); Mirkin (Comment #111); California Optometric Association (Comment #119); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Pentacost (Comment #268); Easton (Comment #432); Koch (Comment #539);

commenters called for an outright ban of the use of such calls.[153] A number of commenters indicate that the automated verification calls are difficult to understand or confusing [154] or do not provide all of the information required to be a valid request.[155] Some optometrists or state optometric associations, many of which consist of or represent small businesses,[156] complain that these calls are too long and time consuming,[157] disturb their practices, take time away from providing care and attention to their patients, and make the phone lines unavailable for their patients.[158] Commenters explained that part of the reason the automated calls are so disruptive is that the caller continuously redials until a message is fully communicated.[159] In response to the recurring disruption, one prescriber stated that his office simply ignores the robocalls.[160]

Other commenters mentioned that sellers provide the patient name several sentences into, or at the very end of, the verification request, making it difficult for prescribers' offices to respond efficiently and to verify the prescription in real time.[161] Some commenters also complained that the automated calls come during business hours when they are busy with patients.[162] Meanwhile, other commenters complain that the calls come in during non-business hours, and express concern that as a result, sellers may release the contact lenses to patients without the prescriber having time to confirm the prescription.[163]

Due to the aforementioned problems with automated telephonic verification requests, the Coalition for Patient Vision Care Safety asserted that prescribers are often unable to provide the proper verification of the patient's prescription information within eight business hours, triggering the passive verification. As a result, patients may receive contact lenses based on outdated or incorrect prescription information.[164] The Coalition stated that ''the fact that patients are receiving contact lenses based on incorrect, outdated, or unverified prescription information runs counter to the FDA's medical device safety standards, and can also lead to serious vision issues.'' [165]

On the other hand, 1–800 CONTACTS requested the Commission retain the use of automated phone systems as an acceptable form of direct communication for verification purposes. It argued that changing the status quo would be ''unjustified, contrary to congressional intent and not in the interest of consumers.'' [166] According to 1–800 CONTACTS, it has experimented with other forms of direct communication and concluded that ''a well-functioning automated system that incorporates the latest technology is the most efficient means of handling the large volume of verification requests that are required today.'' [167] 1–800 CONTACTS indicated it has invested significant resources into the development of a system that is less subject to human error, allows accurate information to be given consistently to every prescriber, and provides assurance that it is compliant with the Rule. The company claimed that its system has an automated voice that is clear and easy to understand, and contains user-friendly options, such as the opportunity to pause the verification script or to request the system call back at a later time. 1–800 CONTACTS'

Connecticut Association of Optometrists (Comment #560); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); American Optometric Association (Comment #644); Rubow (Comment #649); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

[153] *E.g.,* Virginia Optometric Association (Comment #16); Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Easton (Comment #432); New Mexico Optometric Association (Comment #211); Koch (Comment #539); Connecticut Association of Optometrists (Comment #560); Tennessee Association of Optometric Physicians (#575); Colorado Association of Optometrists (Comment #584); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); American Optometric Association (Comment #644); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

[154] *E.g.,* Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Borsky (Comment #26); Matthews (Comment #25); Maanum (Comment #23); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Virginia Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Howe (Comment #53); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); Mirkin (Comment #111); California Optometric Association (Comment #119); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Easton (Comment #432); Koch (Comment #539); Connecticut Association of Optometrists (Comment #560); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); American Optometric Association (Comment #644) (stating they have often received complaints over the last ten years from optometrists that robocalls from 1–800 CONTACTS were difficult to understand); Rubow (Comment #649) (stating that if the entire recorded message is not completed within the allotted time on the answering machine, they then receive a message from an actual live person where the person speaks so fast that it requires playing back the message four or five times in order to get all the information); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669);Vo (Comment #673).

[155] Virginia Optometric Association (#46); Iowa Optometric Association (Comment #79) (stating robocalls too often provide incomplete information); Hicks (Comment #256); Pentacost (Comment #268) (stating automated messages start playing well before the voicemail begins recording so that the office does not catch the name of the patient or which company left the message); Connecticut Association of Optometrists (Comment #560) (stating robocalls too often provide incomplete information); Coalition for Patient Vision Care Safety (Comment #621) (stating robocallers leave voice messages without contact information and may be cut off before conveying in entirety the patient's information); American Optometric Association (Comment #644) (stating they have often received complaints over the last ten years from optometrists that robocalls from 1–800 CONTACTS did not include all of the necessary information to confirm a prescription).

[156] *E.g.,* Pennsylvania Optometric Association (Comment #46); Iowa Optometric Association (Comment #79); Connecticut Association of Optometrists (Comment #560); Tennessee Association of Optometric Physicians (Comment #575); Rubow (Comment #649).

[157] *E.g.,* Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Iowa Optometric Association (Comment #79); Lai (Comment #620); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Plumb (Comment #219); Hicks (Comment #256); Leach (Comment #257); Chang (Comment # 258); Easton (Comment #432); Koch (Comment #539); Tennessee Association of Optometric Physicians (#575); Lueng (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Coalition for Patient Vision Care Safety (Comment #621); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); American Optometric Association (Comment #644); Vo (Comment #673).

[158] Easton (Comment #432); Louie (Comment #657). *See also* Iowa Optometric Association (Comment #79) (explaining the need to protect small businesses from disruptive calls that interfere with treating patients and tie up phones); Pham (Comment #232); Tennessee Association of Optometric Physicians (Comment #575); Michigan Optometric Association (Comment #86).

[159] *See, e.g.,* Wisconsin Optometric Association (Comment #30); Pennsylvania Optometric Association (Comment #46); New Mexico Optometric Association (Comment #211); Tennessee Association of Optometric Physicians (Comment #575).

[160] Scolin (Comment #369).

[161] Brauer (Comment #68); Kalman (Comment #150); Egger (Comment #163); Plumb (Comment #219); Rosemore (Comment #468).

[162] *See, e.g.,* Chang (Comment #126); Scolin (Comment #369); Tennessee Association of Optometric Physicians (#575).

[163] Connecticut Association of Optometrists (Comment #560); Colorado Optometric Association (Comment #584).

[164] Comment #621. *See also* Iowa Optometric Association (Comment #79); Chakuroff (Comment #189); Bricker (Comment #195); Spaeth (Comment #486).

[165] Comment #621.

[166] Comment #568.

[167] *Id.*

comment also noted that, while its messages are automated, calls are initiated by live agents to guarantee that all calls are placed to the intended prescribers.[168] 1–800 CONTACTS also asserted that when a message is left on an answering machine, the live agent remains on the line during the entire automated message to ensure that the complete message is conveyed to the prescriber.[169]

According to 1–800 CONTACTS, each week it places approximately 100,000 calls to prescribers to verify prescriptions. The complete phone script for an automated verification call from 1–800 CONTACTS is 2 minutes, 29 seconds (149 seconds) in length, and prescribers familiar with the system have the option to skip the first 48 seconds of the message to reduce the total time of the message to 1 minute, 41 seconds (101 seconds). 1–800 CONTACTS indicated that the average prescriber receives only one verification request per week from the company,[170] and the highest volume office in its records received, on average, six verification requests per week in 2014.[171] The company explained that it places verification calls as it receives orders, and that it receives orders 24 hours a day, seven days a week, with many orders coming in on weekends or during evening hours. The company further explained that it leaves verification messages shortly after its receipt of orders because a continuous call process is ''logistically efficient and prevents a shipping bottleneck at a single hour each day.'' [172]

Regardless of when it places the verification call to the prescriber, however, 1–800–CONTACTS stated that it never ships an order under the passive verification system before passage of eight business hours. The company added that in almost 30% of verification requests, prescribers hang up on verification calls.[173]

The Commission did not receive other comments from contact lens sellers about their use of automated verification systems to verify prescriptions.[174] Consumers Union, the policy and advocacy division of Consumer Reports, also commented in support of automated calling systems, stating that such systems, of which eye doctors should now be aware, are a reasonable means for a retailer to efficiently handle a large volume of prescription requests. Consumers Union also stated that most eye doctors' offices have automated answering systems and it believed they could set up an efficient means for recording the verification request information without significant burden.[175]

The Act expressly authorizes sellers to send prescription verification requests by direct communication [176] and defines ''direct communication'' to include communication by telephone, facsimile, or electronic mail.[177] In previously considering this issue, the Commission noted that telephone is commonly understood to include automated telephone systems. The Commission therefore concluded in the initial rulemaking that ''it would thus seem to be contrary to Congressional intent to prohibit the use of this technology.'' [178] Nevertheless, then and now, the Commission emphasizes that automated telephone systems must fully comply with all applicable Rule requirements in order to transmit valid verification requests.

For example, any automated verification request must provide complete verification request information as required under section 315.5(b),[179] and this information must be either received by a person on the telephone or otherwise received in full (*e.g.,* all of the requisite information is left on a telephone answering machine). A request delivered by an automated telephone system does not comply with the Rule if it is not delivered in a volume and cadence that a reasonable person can understand, or if it contains incomplete verification information. The seller must also allow eight business hours for the prescriber to respond. During the initial rulemaking in 2004, the Commission indicated that it would ''continue to monitor whether full, valid requests for verification of a prescription are being made through the use of automated telephone systems'' and may revisit the issue ''[i]f evidence demonstrates that sellers are not making valid verification requests but are providing consumers with contact lenses despite deficient requests.'' [180]

The comments submitted in this Rule review by optometrists, students of optometry, and their trade associations provide the Commission with some evidence that some prescribers are receiving incomplete or otherwise inadequate verification requests. In addition, the Coalition for Patient Vision Care Safety asserted there is substantial evidence that verification requests are deficient and the American Optometric Association claimed that problems with 1–800 CONTACTS' automated verification systems are often reported by its members.[181] However, commenters did not provide any empirical data regarding the frequency of these various practices, average or aggregate costs associated with automated calls in particular, or the number of illegal or otherwise deficient contact lens sales that result from such calls. Furthermore, the Commission lacks evidence indicating whether these problems occur with automated calls generally or are chiefly associated with only one or a small group of sellers. If the reported problems chiefly are associated with the practices or systems of a limited number of sellers, the Commission would consider education of, or enforcement against, such sellers, rather than an amendment to the Rule at this time.[182]

Incomplete or incoherent verification requests are not valid verification requests.[183] However, a seller may not always realize that it has made an invalid request and, hence, might dispense lenses under an assumption of

[168] *Id.*

[169] *Id.*

[170] However, if the call is not completed, 1–800 CONTACTS will call the prescriber again. Therefore, one verification request may result in more than one call.

[171] *Id.*

[172] *Id.*

[173] Comment #187. *See also* Consumers Union (Comment #677) (calling prescriber hang-ups a reported problem).

[174] Warby Parker, an online seller of eyeglasses, commented on its support of the use of automated phone systems as a form of direct communication for verification purposes. Comment #593.

[175] Comment #677.

[176] 15 U.S.C. 7603(a)(2).

[177] 15 U.S.C. 7603(g).

[178] 69 FR at 40489.

[179] When seeking verification of a prescription, the seller must provide the prescriber with: The patient's full name and address; the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; the quantity of lenses ordered; the date of patient request; the date and time of verification request; the name of a contact person at the seller's company, including facsimile and telephone numbers; and, if the seller is counting the prescriber's regular Saturday hours as ''business hours,'' a clear statement of the prescriber's regular Saturday business hours. 16 CFR 315.5(b).

[180] 69 FR at 40489.

[181] Coalition for Patient Vision Care Safety (Comment #621); American Optometric Association (Comment #644).

[182] In fact, a number of state optometric associations note that the costs prescribers' offices expend related to the Rule are most often due to incomplete or otherwise inadequate verification requests. Michigan Optometric Association (Comment #86); Wisconsin Optometric Association (Comment #30); Pennsylvania Optometric Association (Comment #46); Iowa Optometric Association (Comment #79); New Mexico Optometric Association (Comment #211). Thus, education and enforcement efforts to improve sellers' compliance with the verification aspects of the Rule may have a large benefit for prescribers, without the need to prohibit automated verification calls.

[183] 69 FR at 40496 (''The Commission emphasizes that the sale of contact lenses based on a verification request which does not contain all of the required information constitutes a Rule violation.'').

passive verification if the prescriber does not contact the seller within eight business hours of the invalid request. Accordingly, to prevent the improper dispensing of lenses, the Commission encourages prescribers to contact the seller in these circumstances to inform them that the request is invalid and state the basis for the invalidity. Once the prescriber communicates that the request is invalid and states the basis for the invalidity, the seller shall not fill the order. Alternatively, for incomplete requests, the Commission encourages prescribers, to the extent they are able, to complete the missing information in order to facilitate the dispensing of the contact lenses.

The Commission is sensitive to the business concerns of the prescribers who complain about the burden and inconvenience they experience from the sellers' use of automated telephone systems. However, the Commission has not seen convincing evidence that the volume of automated verification calls they receive each day presents a burden that is not outweighed by the competitive benefits of the Rule, or that these practices frequently result in illegal sales of contact lenses. If the Commission receives evidence of a compelling widespread problem, it may revisit its position on the use of automated verification requests.[184] At this point, however, the Commission declines to prohibit the use of automated verification calls.

Nevertheless, the Commission encourages sellers, to the extent possible, to consider whether they could alleviate some of the commenters' concerns by modifying their automated telephonic verification procedures or, alternatively, by increasing the use of other permissible communication methods. The Commission also seeks additional information on possible modifications to the Rule that, short of prohibiting automated verifications calls, could address the issues raised by commenters relating to these calls.

The Commission declines to restrict when sellers may place automated phone verification calls. As long as sellers are placing valid and complete verification requests, and are not shipping orders prior to active verification, or the passage of eight business hours, automated telephone verification requests placed outside of a prescriber's business hours comply with the Rule. Moreover, a review of the comments reveals that some prescribers object to calls during office hours, while others object to calls during evening and weekend hours. The Commission therefore does not propose, at this time, to limit the time period when sellers may place automated calls.

B. Section 315.5(b)—Information for Verification

Section 315.5(b) delineates the information required for a prescription verification request: (1) Patient's full name and address; (2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; (3) the quantity of lenses ordered; (4) the date of patient request; (5) the date and time of verification request; (6) the name of a contact person at the seller's company, including facsimile and telephone numbers; and (7) if the seller opts to include the prescriber's regular business hours on Saturday as ''business hours'' for purposes of computing the eight business hour calculation, a clear statement of the prescriber's regular Saturday business hours.

1. Vendor Contact Information

A few individual prescribers stated that they were unable to contact vendors in order to get additional information when the verification request was incomplete.[185] The American Optometric Association also voiced concerns about the difficulty that prescribers have in reaching an individual at 1–800 CONTACTS to discuss prescription concerns.[186] Several state optometric associations asserted that physician small businesses may spend significant time on hold or attempting to use various phone numbers or automated prompts to reach a live person. These commenters recommended that the Commission require larger contact lens retailers to make available more than one individual at a company to act as the contact person for physician questions and concerns.[187] Commenters did not explain the nature of the incomplete verification requests such that a live person was necessary to address the inadequacy of the request, nor did they elaborate upon the reasons why prescribers need to reach live persons at contact lens retailers to answer ''questions and concerns.''

The Commission declines to propose this Rule modification. The Rule requires that the seller provide the name of a contact person at the seller's company, including facsimile and telephone numbers.[188] In requiring a facsimile number as well as a telephone number, it is clear that the Act and the Rule intended to provide for direct communication, but not necessarily contemporaneous, live communication. The language of the Act and the Rule anticipates that some sellers will communicate with prescribers via live agents, but does not require it. Instead, the Act and the Rule allow sellers also to communicate with prescribers about verification requests via facsimile as well as voicemail.

Furthermore, the Commission does not believe it is necessary to require large contact lens retailers to have more than one individual available for prescriber questions and concerns, as long as a contact person is ''reasonably accessible to the prescriber.'' [189] As discussed in the initial rulemaking, the vendor contact provision is intended to ensure that the prescriber is able to reach a responsible person at the seller's company.[190] No evidence was presented showing how often prescribers experience difficulty in obtaining reasonable access to a contact person at the seller's company.[191] Without such

[184] The Commission notes that since Congress expressly permitted telephone as a form of direct communication for verification, if the Commission were to prohibit automated telephone calls, more live communications might result. Such communications would not necessarily alleviate all of the concerns expressed by commenters and might cause more problems for sellers with a large volume of orders and/or a small amount of staff.

[185] Truong (Comment #55); Cervantes (Comment #479).

[186] Comment #644.

[187] Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

[188] 16 CFR 315.5(b)(6).

[189] 69 FR at 40497.

[190] *Id.* The Rule also requires that during the eight-business-hour window, ''the seller shall provide a reasonable opportunity for the prescriber to communicate with the seller concerning the verification request.'' 16 CFR 315.5(c)(3). In the initial rulemaking, the Commission declined to articulate with specificity the equipment or personnel that sellers must have to handle verification requests, in order to give sellers the flexibility to determine the most effective and efficient means of providing the opportunity to communicate. Rather, the Commission promulgated the final Rule to require that sellers provide prescribers a ''reasonable opportunity'' for the prescriber to communicate with the seller. 69 FR 40499.

[191] Likewise, the Commission did not receive evidence sufficient to show that the methods for communication offered by sellers do not provide prescribers with a reasonable opportunity to

Continued

evidence, the Commission cannot determine whether a modification of the Rule is necessary.

Moreover, as discussed earlier,[192] if a verification request is incomplete, the request is invalid. If the prescriber communicates to the seller within the Rule-specified deadline that the verification request or the prescription is invalid,[193] the seller may not fill the prescription.[194] It is not necessary to reach a live person to perform this function. Once alerted that a verification request is invalid and the reason for the invalidity, the burden falls on the seller to resolve the invalidity, if possible. In addition, in routine cases it would not be necessary to reach a live person in order to correct a prescription. Accordingly, the rulemaking record contains insufficient evidence to show that mandating a mechanism for contemporaneous live communications is necessary to carry out the Act.

The American Optometric Association also urged the Commission to amend the Rule to require sellers to respond to prescriber questions within an eight-business-hour window, or cancel the sale without verification. The Association's comment did not explain the types of concerns that prescribers need to discuss with live agents at contact lens retailers. This proposal would require that once a prescriber contacted a seller with concerns, the seller could not assume the prescription was verified. Instead, the seller would be required to personally contact the prescriber and discuss the concerns within eight business hours, or cancel the sale.[195]

The Commission declines to propose this modification as well. As discussed above, neither the Act nor the Rule requires contemporaneous, live communication between prescribers and sellers. Furthermore, the Commission believes that such a requirement would undercut the Act's passive verification framework. Such a mechanism could conceivably allow any prescriber to lodge a concern or question and thereby halt the passive verification mechanism. As discussed above, if the prescription verification request is incomplete or inaccurate, or if the prescription is expired or otherwise invalid, the prescriber may alert the seller. The seller cannot fill a prescription if the prescriber has indicated that the prescription is expired or otherwise invalid.

2. Prescribers' Selection of Communication Mechanism

A few commenters suggested that the prescriber should have the ability to choose the method of communication sellers use to communicate verification requests with their offices.[196] One commenter stated that she requested a seller make all future verification requests through facsimile, but the seller, who sometimes made requests via facsimile, refused her request.[197] A number of prescribers expressed a preference for sellers to use another type of communication to verify contact lens prescriptions, including facsimile or email.[198] A few prescribers requested that sellers use live telephone calls to communicate with their offices.[199] The concept of having prescribers select the communication method that the seller would use to verify a prescription (*i.e.* by telephone, fax, or online) was previously raised with the Commission during the initial rulemaking.[200] As the Commission then determined, because the Act defines ''direct communication'' to include three different communication mechanisms that sellers may use—telephone, facsimile or electronic mail—the Act does not permit prescribers to limit the communication mechanisms sellers may use to submit verification requests.[201] Nevertheless, nothing prevents a seller from honoring a prescriber's request for a certain type of communication and the Commission suggests that sellers evaluate whether honoring such requests would increase the speed and efficiency of the verification process.

C. Section 315.5(c)—Verification Events

Section 315.5(c) sets forth the three circumstances under which a seller can consider a prescription ''verified by direct communication'' and proceed to sell contact lenses to its customer: (1) The prescriber confirms the prescription is accurate by direct communication with the seller; (2) the prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; and (3) the prescriber fails to communicate with the seller within eight business hours after receiving a proper verification request from the seller.[202]

1. Passive Verification

A number of commenters expressed the view that because contact lenses are restricted medical devices, they should not be dispensed unless the prescriber actively verifies the prescription.[203] The Contact Lens Association of Ophthalmologists, for example, in arguing for the elimination of passive verification, stated that it ''puts the health of consumers at risk and is inconsistent with regulatory practices for confirmation of the validity and accuracy of prescriptions for drugs and for other Class II and Class Ill medical devices.'' [204]

Other commenters expressed the concern that the passive verification framework can be manipulated and, therefore, does not adequately ensure that patients receive contact lenses in accordance with proper medical

communicate with the seller about the verification request.

[192] *See supra* Section IV.A.3.

[193] If a prescriber deems a prescription invalid, the Rule requires that the prescriber specify the basis for the invalidity. 16 CFR 315.5(d).

[194] In addition, Warby Parker proposed that the Commission include stronger language in the Rule to make clear that it is a violation for prescribers to respond to a verification request by stating that prescription information is incorrect when, in fact, it is not; or to respond to a verification request by stating that prescription information is inaccurate or invalid without providing the basis for the inaccuracy or invalidity of the prescription. Comment #593. The Rule already provides that if a prescriber indicates that a prescription is inaccurate or invalid, the prescriber shall specify the basis for doing so. A failure to do so violates the Rule. *See* 16 CFR 315.5(d). Further, falsely indicating that a prescription was inaccurate would essentially equal a failure to ''correct'' a prescription, as mandated by the Rule and therefore, also would be a violation. *See id.* The Commission does not believe it needs to clarify these prescriber obligations further. Warby Parker also proposed that the Commission clarify that it is a violation of the Rule for a prescriber to interfere, in any way, with a seller's effort to verify a prescription. This proposal is not described in detail nor is the frequency of this problem supported with empirical evidence. The Commission therefore declines to propose this Rule modification.

[195] Comment #644.

[196] Filandro (Comment #129); Chakuroff (Comment #189); Stuart (Comment #635).

[197] Chakuroff (Comment #189).

[198] Mirkin (Comment #111) (stating that fax or email verifications are quick and easy to answer); Chang (Comment # 126) (requesting fax or email verification system); Filandro (Comment #129) (requesting sellers offer all offices fax option for verification requests); Koch (requesting use of fax); Rubow (Comment #649) (seeking a requirement that online retailers verify through a route that is intelligible, including fax or a live person). *But see* Hicks (Comment #256) (stating automated fax systems are difficult for their offices as the fax machine is in an area of the business that is not frequently used); Ambler (Comment #524) (complaining of receipt of poor quality faxes when the office is closed).

[199] Mirkin (Comment #111); Hicks (Comment #256) (stating a simple, quick phone call is much easier and would result in faster turnaround times for the patients); Rubow (Comment #649).

[200] 69 FR at 40497.

[201] *See* 15 U.S.C. 7603(g).

[202] 16 CFR 315.5(c).

[203] California Optometric Association (Comment #119) (''Contact lenses are medical devices. Therefore, it is reasonable to replace passive verification with active verification for contact lenses.''); Weissman (Comment #50) (same); Bainbridge (Comment #152) (''Start treating contact lenses like the medical devices they are and start respecting the clinical judgment of doctors.'').

[204] Comment #572.

oversight. For example, some commenters asserted that passive verification is problematic because patients, in some circumstances, may be able to obtain lenses by providing fictional or incorrect information to sellers.[205] A common scenario relayed by commenters is that if the patient provides the seller with the name of a fictional prescriber and a fictional fax number, the prescription will be passively verified when there is no response within eight hours.[206]

Some prescribers reported instances where some patients were never seen by a prescriber, and apparently the consumer just pulled the prescriber information from a Web site in an attempt to get a prescription verified via passive verification.[207] A few commenters reported that patients said they were instructed—by sellers—to use any optometrist name, or any facsimile number, in order to facilitate the order.[208] A few commenters also complained that after they have flagged a verification request as invalid, some sellers try to game the system and trigger a passive verification by then repeatedly faxing the same verification request to the prescriber in the hopes that the prescriber will not have the opportunity to deny the verification request again, and it will end up passively verified.[209]

In light of these concerns, some commenters concluded that the passive verification system is not working as intended to protect patient eye health and instead, recommended that all contact lens prescriptions be actively verified.[210] One commenter recommended that the Rule be modified to prevent the shipping of contact lenses without active verification.[211] Another commenter said that if the retailer has not received an image of the actual prescription, the seller should at least obtain some confirmation that the customer is genuinely a patient of the prescriber that is being contacted for verification.[212]

The Commission declines to propose these Rule modifications. Issues identical to these were raised during the initial rulemaking process in 2004, when commenters either opposed or expressed significant concern about the passive verification system imposed by the Act and the Rule.[213] At that time, some commenters were concerned about the use of a passive verification system for prescription medical devices such as contact lenses. Other commenters, during the initial rulemaking, expressed concern that verification requests could be sent to the wrong prescriber and might be improperly filled via passive verification because the prescriber neglected to respond to it.[214]

The Commission responded to concerns about passive verification by finding that ''[b]ecause Congress has decided to impose a passive verification system through the Act, whether to adopt a passive verification system is not at issue in this rulemaking proceeding.'' [215] The same holds true today, and this rule review does not revisit the decision to include a passive verification system.

With respect to concerns that patients are manipulating the passive verification system by deliberately providing inaccurate prescriber information, the Commission notes that if prescribers receive verification requests for individuals who are not their patients, prescribers have the ability and incentive to respond that such requests are ''invalid'' under section 315.5(d) of the Rule,[216] thus preventing an improper passive verification.

With regard to concerns that patients are deliberately providing fictional prescriber information and fictional contact information, commenters produced only anecdotal evidence of such actions, and did not provide empirical data regarding the frequency of these activities. Although it is possible that such activities could allow some patients to obtain contact lenses without a valid prescription, the Commission notes that in doing so, such individuals are intentionally circumventing the Rule. As discussed above, the passive verification framework has been mandated by Congress in an effort to balance the interests of consumer health and prescription portability. At the time the Act was under consideration, Congress was aware—after being informed by the Commission and the American Optometric Association, among others—that passive verification was not a foolproof method for preventing the verification of invalid prescriptions.[217] The Commission will consider consumer education efforts designed to encourage consumers to act responsibly,

[205] Wang (Comment #94) (discussing ''deliberate attempts to evade verification with the knowledge that a lack of verification is equivalent to a prescription being verified''); Anklin (Comment #107) (describing the use of incorrect or even falsified information); Filandro (Comment #129) (noting that patients can fax the request to their own home or email); Stewart (Comment #136) (patients are able to use any fax number); McCutchan (Comment #624) (describing use of fax numbers for practices that are no longer active).

[206] Caughell (Comment #7); Truong (Comment #55); Navarro (Comment #117); Zierlein (Comment #123); Ammon (Comment #128); Ciszek (Comment #134); Lee (Comment #158); Ambrose (Comment #196); Ahmed (Comment #209); Dell (Comment #227); Williston (Comment #252); Pentecost (Comment #268); Smith (Comment #319); Makler (Comment #356); Bolenbaker (Comment #357); McWilliams (Comment #362); Diaz (Comment #380); Liebig (Comment #478); Balitski (Comment #485); Garcia (Comment #511); Loerzel (Comment #550); Pham (Comment #641); Lisenby (Comment #662).

[207] Driesen (Comment #47); Howe (Comment #53); Cherian (Comment #89); Hosaka (Comment #240); Chavez (Comment #334); Ling (Comment #390); Redder (Comment #454); Nakasone (Comment #469); Ball (Comment #590); Heuer (Comment #467); Ostrom (Comment #489); Hartman (Comment #522); Milsky (Comment #559).

[208] Sadeghian (Comment #242) (''A number of patients tell me that it is common practice by these online contact lens companies to tell the consumer to leave [the consumer's] fax number as the doctor's fax so nobody would respond to their requests.''); Alianiello (Comment #253) (''I asked where he's been buying contact lenses and he told me the online avenue he uses asked him for his doctor's name, and when he told them he couldn't spell my last name they told him to look in the phone book and give them a name of an optometrist and they'd take care of it.'').

[209] *See, e.g.,* Christensen (Comment #149).

[210] Driscoll (Comment #67); Diaz (Comment #380); Whittington (Comment #443).

[211] Palmer (Comment #484).

[212] Milsky (Comment #559). This commenter also proposed that in order to allow eye doctors and the Commission to be able to track in detail what happens to online orders after the verification request is sent, the seller should be required to inform the prescriber whether the transaction was cancelled or completed, and if so, what exactly was shipped and when. This mechanism would document whether lenses were shipped before any verification took place.

[213] 69 FR at 40497 and note 206.

[214] 69 FR at 40497 and note 198.

[215] 69 FR at 40497.

[216] *Id.*

[217] *See, e.g.,* ''Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,'' 108th Cong. 1 (Sept. 12, 2003) (Testimony of J. Pat Cummings, American Optometric Association) (testifying that ''the problem with passive verification'' is that some people will be able to get contact lenses without a prescription); *id.* (Testimony of Howard J. Beales, Federal Trade Commission) (noting that passive verification contains a risk that some contact lenses will be provided based on out-of-date prescriptions). Congress opted for passive verification after hearing repeated reports of the difficulties consumers confronted having prescriptions verified in states with active verification systems. *See* H.R. Report No. 108–318, at 5 (2003) (stating the Fairness to Contact Lens Consumers Act ''adopts a passive verification system in order to best serve the consumer,'' after hearing testimony from consumers and businesses of the ''unusually high number of consumer complaints in states that rely on active verification schemes.''). *See also* ''Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,'' 108th Cong. 1 (Sept. 12, 2003) (Testimony of Peggy Venable, Texas Citizens for a Sound Economy) (testifying that under an active verification system in Texas, there was a ''widespread practice [by optometrists] of failing to verify the prescription''); *id.* (Testimony of Jonathan C. Coon, 1–800 CONTACTS) (testifying that under active verification, 1–800 CONTACTS had to cancel half of all orders in Texas due to prescribers' failure to respond to verification requests).

within the confines of the Rule. In addition, to the extent that the Commission receives evidence that sellers are encouraging consumers to provide inaccurate or fictional prescriber information, the Commission will investigate such allegations, as appropriate.

#2. Issues Regarding the Eight-Business-Hour Window

Some commenters stated that the current eight-business-hour window is a reasonable length of time for prescribers to respond to verification requests.[218] 1–800 CONTACTS, for example, asserted that the ''eight business-hour time frame for passive verification gives prescribers sufficient time to confirm important health information and correct any inaccurate orders without imposing a needless delay on consumers who place a premium on quick delivery.'' [219] As support, 1–800 CONTACTS stated that last year it cancelled orders worth approximately $40 million in response to communications from prescribers, and that the ''number of deleted orders and the value of sales cancelled demonstrate that prescribers have more than adequate time to respond when necessary.'' [220]

Other commenters, however, argued that the eight-business-hour time frame for passive verification does not allow enough time for doctors to notify sellers that a prescription is expired, inaccurate, or nonexistent. The American Academy of Ophthalmology, for example, stated that the eight-business-hour requirement ''is far too short and ultimately imposes significant burdens on providers and in many instances eliminates a necessary patient safety check.'' [221] Some prescribers noted that their offices are very busy and that eight business hours was not enough time to verify prescriptions.[222] The CLAO suggested that eight business hours was insufficient because ''validation requests arrive with incomplete or erroneous patient information complicating the process by which clinical records are retrieved.'' [223] These comments, however, did not quantify how the eight-business-hour time frame imposed ''significant burdens'' on providers, nor establish that a significant number of prescribers were unable to respond to verification requests within eight business hours. Commenters similarly failed to provide specific information quantifying the frequency of incomplete or incorrect validation requests.

Many commenters did not propose a specific extension of time to respond to a verification request,[224] and merely stated that eight business hours was not enough. Some commenters did put forth specific proposals, such as changing the language to ''eight (8) business hours or twenty-four (24) clock hours, whichever is later,'' [225] doubling the length of time to 16 hours,[226] or extending the verification window to at least two business days.[227] Others suggested providing at least 48 to 72 hours,[228] or two to three business days,[229] to confirm the validity of a prescription. A few commenters suggested that increasing the window to 72 hours would alleviate issues that arise when verifications are received on Friday, Saturday or Sunday.[230]

Having considered these comments, the Commission declines to propose a Rule modification lengthening the eight-business-hour timeframe during which a prescriber must respond to a verification request. Despite comments that the timeframe is too short, the Commission believes that the current eight-business-hour time frame is adequate for the vast majority of prescribers. Commenters put forth no empirical evidence that prescriptions are being improperly verified via passive verification due to prescribers not having enough time to respond, and cited no compelling changes in the marketplace that would justify extending the time frame beyond eight business hours. If anything, because of advances in technology, electronic communications, and record-keeping, eight business hours is as appropriate, if not more so, than when implemented in 2004. As the Commission explained in the initial rulemaking, ''Congress recognized that consumers may be harmed if they face undue delays in receiving their contact lenses from a seller'' and balanced that consideration against the possible harm consumers may experience if sellers provide contact lenses based on invalid prescriptions.[231] The Commission has found nothing thus far in the record for this rule review proceeding to disturb that determination.

In addition to concerns about the time prescribers have to respond, some commenters expressed concern about when verification calls are placed and received. Some optometrists expressed concern that some sellers are exploiting the Rule by placing verification requests after hours in order to circumvent the eight-business-hour window.[232] Other prescribers noted with frustration that sellers fax verification requests outside of normal business hours, such as in the middle of the night or on weekends, thereby making it impossible for them to respond in a timely fashion.[233] Some commenters complained that because they only had 24 hours to respond to a

[218] 1–800 CONTACTS (Comment #568). *See also* Warby Parker (Comment #593) (''Passive verification provides prescribers with a reasonable opportunity to verify, address or correct an inaccurate, invalid or expired prescription without imposing an undue burden on the prescriber. Furthermore, it gives the seller a reasonable end-point at which to proceed with the sale. This ensures that prescribers do not thwart patient choice of where to purchase contact lenses by failing to verify a prescription and relegating the patient back to the prescriber for the ultimate purchase. We also believe that eight business hours is a reasonable length of time for passive verification.'').

[219] Comment #568.

[220] *Id.*

[221] Comment #611.

[222] Tran (Comment #260); Bierwerth (Comment #308); Loerzel (Comment #550); Fink-Freeman (Comment #609).

[223] CLAO (Comment #572).

[224] Whittington (Comment #443) (''more than eight hours to confirm the RX request''); Heuer (Comment #467) (''reasonable amount of time to respond'').

[225] Milsky (Comment #559) (''That change would still not prevent the situation where, for example, a verification request comes in on a holiday weekend and the prescriber's office is closed for an extra day off, or when a practice is not open on Wednesdays, but at least it would mean that the prescriber would have a little more of an opportunity (especially at the beginning or end of the workday) to correct any errors in the verification request, before the order is shipped and it's too late.'').

[226] Kiener (Comment #74); Perala (Comment #315); Diaz (Comment #380).

[227] CLAO (Comment #572); Koury (Comment #573); Fink-Freeman (Comment #609); American Academy of Ophthalmology (Comment #611). *See also* Hua (Comment #45) (recommending an increase to 24 to 48 hours); Bhadra (Comment #105) (same).

[228] Gooderman (Comment #10); Galdamex (Comment #167) (at least 72 hours); Lin-Dilorinzo (Comment #476); Espy (Comment #587).

[229] Voight (Comment #551); Figazolo (Comment #24) (three days); Truong (Comment #55) (three days).

[230] Yaklich (Comment #364); Raff (Comment #373). *See also* Coalition for Patient Vision Safety (Comment #621).

[231] 69 FR at 40482.

[232] Berger (Comment #200) (''[u]nder the current law, retailers are allowed to fill a prescription if verification is not received within 8 hours. This is commonly exploited by faxing or robodialing verification requests outside of normal business hours, then filling the prescription before the prescriber responds.''). *See also* Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Hodes (Comment #42); Dodge (Comment #44); McBride (Comment #171); Sloan (Comment #177); Kirkconnell (Comment #202); Hamilton (Comment #216); Leach (Comment #257); Chang (Comment #258); Yaklich (Comment #364); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

[233] Plumb (Comment #219); St. Martin (Comment #292); Diaz (Comment #380); Witmeyer (Comment #418); Nakasone (Comment #469); Garcia (Comment #511); Egbert (Comment #515); Steinleitner (Comment #517).

verification request,[234] such verifications would be confirmed automatically over the weekend because no one was in the office.[235] Other commenters noted that they receive verification faxes outside of normal business hours and therefore have no way of verifying, denying, or correcting prescriptions.[236] Many of these commenters recommended that the Rule be amended to prohibit sellers from sending prescription verifications after business hours and on weekends.[237] Along the same lines, the Coalition for Patient Vision Safety recommended that the Commission modify ''the eight-hours of communication when the initial communication begins prior to a holiday or on a weekend when the doctor is not conducting normal office hours.'' [238]

At this time, the Commission does not propose to amend the Rule to prohibit sellers from sending prescription verification requests after business hours and on weekends or to otherwise extend the eight-business-hour window to account for weekends and holidays. It appears that the majority of commenters suggesting this prohibition are concerned that they do not have the opportunity to verify a prescription because they believe the eight-business-hour window for verification of a contact lens order is triggered upon receipt of a verification request, no matter when that request is received. That concern is misplaced. Section 315.2 of the Rule provides that ''[f]or verification requests received by a prescriber during nonbusiness hours, the calculation of 'eight (8) business hours' shall begin at 9 a.m. on the next weekday that is not a Federal holiday or, if applicable, on Saturday at the beginning of the prescriber's actual business hours.'' [239]

Other commenters expressed frustration that verification requests were sent after regular business hours with the statement that the prescription would be filled unless the prescriber contacted the seller within 12 to 24 hours.[240] Depending upon when these requests are sent, these sellers' practices could result in contact lenses being shipped before or after the end of the eight-business-hour window. To the extent that sellers are dispensing contact lenses prior to the end of the eight-business-hour window, the Commission notes that this practice violates the Rule. If the Commission receives evidence that sellers are dispensing contact lenses before the end of the eight-business-hour window, the Commission will investigate such allegations, as appropriate.

A few commenters expressed concern that some prescriptions were being automatically filled without a prescriber's oversight because the calculation of an eight-business-hour window does not take into consideration the fact that their offices may not be open or able to verify prescriptions during the Rule's established timeframe for business hours.[241] For example, an office may be closed due to vacation, inclement weather, or regularly scheduled office closures that occur during the normal workweek.[242]

Similar concerns were raised by commenters in the initial rulemaking in 2004. At that time, the Commission declined to adopt an actual hours or other prescriber-specific approach to business hours, noting that ''[i]t likely would be difficult and burdensome—perhaps impossible—for some sellers to determine and keep track of the actual hours of 50,000 prescribers. By contrast, a general rule using a uniform definition of business hours for all prescribers provides clarity and relative ease of compliance and enforcement.'' [243] In addition, the Commission recognized that there ''does not appear to be any practical way to accommodate the myriad circumstances during which the offices of 50,000 individual prescribers may be closed or otherwise not able to respond to a prescription verification request.'' [244] The Commission continues to believe that such an approach would be impractical and declines to propose an actual hours or other prescriber-specific approach to calculating business hours.

V. Contact Lens Prescriptions

A. Section 315.6—Expiration of Contact Lens Prescriptions

As set forth by Section 315.6(a) of the Rule, a contact lens prescription expires on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription.[245] If State law specifies no date or specifies a date less than one year after the issue date of the prescription, the Rule provides that the prescription shall not expire less than one year after the issue date of the prescription.[246] A prescriber, nonetheless, can specify a shorter expiration date if that date is ''based on the medical judgment of the prescriber with respect to the ocular health of the patient.'' [247] The prescriber then must document the reasons in the patient's medical record.[248] In other words, contact lens prescriptions cannot expire in less than one year unless, based on medical judgment, a prescriber specifies a different date and documents the

[234] Whipple (Comment #15); Huang (Comment #17); Wilson (Comment #76); Green (Comment #162); Frederick (Comment #207); Zair (Comment #512).

[235] Magee (Comment #95); Mueller (Comment #513); Born (Comment #570); Shugarman (Comment #266).

[236] Glavine (Comment #62); Tolchin (Comment #194); Bricker (Comment #195); Ahn (Comment #215); Lester (Comment #231); Kegarise (Comment #447).

[237] California Optometric Association (Comment #119); Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Loydall (Comment #225); Leach (Comment #257); Chang (Comment #258); Liebig (Comment #478); Harris (Comment #490); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

[238] Comment #621. Similarly, some commenters suggested increasing the eight-business-hour window because, based on their apparent misunderstanding of how the eight business hours are calculated, they believed that they did not have enough time to respond to verification requests received after business hours and on weekends. *See* Mirkin (Comment #111); Kalman (Comment #150); Bender (Comment #164); Hans (Comment #168); Baur (Comment #170; Yaklich (Comment #364); Raff (Comment #373); Diaz (Comment #380); Kegarise (Comment #447); Heuer (Comment #467); Zair (Comment #512); Gandhi (Comment #588).

[239] *See also* 69 FR at 40486.

[240] Huang (Comment #17); Magee (Comment #95); Green (Comment #162); Shugarman (Comment #266).

[241] A small number of commenters complained that they regularly received verification requests from sellers that state that their records indicate that the prescriber has Saturday business hours. *See* Alianiello (Comment #253); Raff (Comment #373). These commenters said that despite correcting this misimpression, the seller continued to send verification requests that would begin the eight-business-hour window on Saturday morning. The Commission reiterates that this is a Rule violation because the seller only may count Saturday hours as business hours if the seller has actual knowledge of the prescriber's Saturday business hours. Here, the seller has actual knowledge to the contrary. 69 FR at 40485. If the Commission receives evidence of such practices, the Commission will investigate such allegations, as appropriate.

[242] Robins (Comment #165); Glassband (Comment #218); Kubo (Comment #234); Whang (Comment #355); Makler (Comment #356); Falcon (Comment #505); Manuel (Comment #508); Voight (Comment #551); Koury (Comment #573); Kowaleski (Comment #578).

[243] 69 FR at 40484.

[244] *Id.*

[245] 16 CFR 315.6(a)(1). The majority of states require that a contact lens prescription not expire less than one year after the issue date, except when a special medical circumstance necessitates that it expire sooner. A few states, such as Maryland and Washington, require that contact lens prescriptions not expire less than two years after the issue date except for special medical circumstances. *See, e.g.,* Maryland Code § 11–404.4; Wash. Admin. Code § 246–852–010 (1)(f).

[246] 16 CFR 315.6(a)(2).

[247] 16 CFR 315.6(a)(3).

[248] 16 CFR 315.6(b)(1).

reasoning. The language of these Rule provisions closely tracks that of the Act.[249]

1. Length of Contact Lens Prescriptions

The Commission received several comments about the length of contact lens prescriptions. Some commenters expressed the view that the prescription length should be longer. For example, Consumers Union requested that the Commission ''consider whether a longer minimum period is warranted in the best interests of the consumer.'' [250] One consumer commented that contact lens prescriptions should be at least two years in length.[251]

The Professional Opticians of Florida recommended that the Commission modify the Rule to prohibit the use of expiration dates on prescriptions for adult patients with low risk factors,[252] while an optometrist argued that, ''[c]ompetition for the sales of contact lenses is so great that placing any regulations on the length of the prescription is unnecessary and should be at the sole discretion of the prescriber.'' [253] LD Vision Group, a contact lens retailer, declared that while it generally makes sense for patients to undergo a comprehensive eye examination to ensure good eye health, patients should not have to undergo a follow-up contact lens fitting after receiving a trial pair of contact lenses from a prescriber.[254] Furthermore, according to that commenter, patients should be able to waive the requirement that their contact lens prescriptions be verified—and yet still be able to obtain contact lenses—by acknowledging that they are aware of the risks of not obtaining an annual eye examination.[255]

However, many commenters, primarily prescribers, urged the Commission not to ''deregulate'' prescription length [256] or otherwise extend the length of contact lens prescriptions.[257] Other prescribers encouraged the Commission to retain the one-year prescription length, citing the importance of annual eye examinations for preventing complications related to contact lens use, diagnosing other conditions by examining the eyes, and providing patient education about contact lens use.[258] A few commenters expressed satisfaction with the two-year prescription length imposed by some States' laws.[259]

The Commission declines to propose any changes—either removing or lengthening—the Rule's prescription length provisions. As indicated above, the Rule's language closely tracks that of the Act, which set a minimum expiration date ''to prevent prescribers from selecting a short expiration date for a prescription that unduly limits the ability of consumers to purchase contact lenses from other sellers, unless medical reasons justify setting such an expiration date.'' [260] Accordingly, the Commission is not at liberty to remove the prescription expiration provision. In addition, the Commission declines to propose to lengthen the Rule's prescription expiration provisions and believes the current framework is appropriate. As the Commission concluded in response to commenters arguing for a minimum expiration date of two years during the initial rulemaking, in drafting the Act, Congress intended to defer to applicable State law except where such law establishes an expiration period of less than one year.[261]

2. Expired Contact Lens Prescriptions

A number of prescribers reported that some of their patients are obtaining contact lenses through online vendors even though their contact lens prescriptions have expired.[262] According to Johnson & Johnson Vision Care, Inc., ''roughly one-in-three online contact lens purchasers'' surveyed in a 2015 APCO Insight online survey ''admit[ted] to ordering lenses using an already expired prescription.'' [263] In response to these concerns, some commenters recommended that the Commission amend the Rule specifically to prohibit the sale of contact lenses to patients with expired prescriptions.[264]

After reviewing the comments, the Commission has determined that no amendment is necessary because the current regulatory framework sufficiently prohibits the use of expired prescriptions. As a threshold matter, Section 4(e) of the Act and Section 315.5(d) of the Rule clearly identify three categories of invalid prescriptions (inaccurate, expired, and otherwise invalid).[265] Accordingly, the Act and the Rule already make explicit that an expired prescription is not a valid prescription. Under the Rule, sellers may only dispense lenses using either a prescription that has been presented to the seller, or a prescription that has been verified with the prescriber by the seller.[266] A prescription presented to the

[249] 15 U.S.C. 7604.

[250] Comment #677.

[251] Schodowski (Comment #65).

[252] Comment #563.

[253] Bolenbaker (Comment #357).

[254] LD Vision Group (Comment #544).

[255] *Id.*

[256] Wood (Comment #37); Compton (Comment #275); Singhai (Comment #281).

[257] *See, e.g.,* Morgan (Comment #144); Stoliker (Comment #286); Parikh (Comment #288); Shlosman (Comment #290); Lee (Comment #293); Paulsen (Comment #296); Turano (Comment #303); Yang (Comment #307); Daniel (Comment #310); Huynh (Comment #313); Stetson (Comment #314); Theroux (Comment #317); Wong (Comment #330); Tarr (Comment #344); Peres-Maes (Comment #346); Dronka (Comment #347);Scott (Comment #354); Cantor (Comment #358); Cesar (Comment #359); Philippe (Comment #365); Geller (Comment #370); Uchida (Comment #403); Sharma (Comment #404): Nguyen (Comment #412); Eng (Comment #414); Frady (Comment #440); Santhanam (Comment#444); Calhoun (Comment #446); Howard (Comment #453); Desai (Comment #462); Douglas (Comment #526); Geiger (Comment #598); Ancona (Comment #650); Webster (Comment #670).

[258] *See, e.g.,* Coalition for Patient Vision Care Safety (Comment #621);Williford (Comment #38); Kapoor (Comment #58); Anderson (Comment #96); Tse (Comment #146); Morrison (Comment #239); Major (Comment #263); Uy (Comment #277); Williams (Comment #261); Walker (Comment #283); Murray (Comment #287); Rice (Comment #295); Harris (Comment #305); Cluff (Comment #309); Hollister (Comment #318); Oliver (Comment #323); Gelman (Comment #326); Cox (Comment #336); Zimmerman (Comment #372); Sherman (Comment #375); Klein (Comment #377); Hafford (Comment #383); Blankenship (Comment #395); Elmore (Comment #396); Assell (Comment #397); Yaryan (Comment #401); Stefanovic (Comment #417); Enochs (Comment #423); Moore (Comment #437); Archibald (Comment #438); Lott (Comment #445); Goller (Comment #448); Eggers (Comment #473); Abbott (Comment #497); Nazario (Comment #518); Neuenfeldt (Comment #542); Maino (Comment #555); Bieter (Comment #602); Lac (Comment #631); Bandy (Comment #643); Lee (Comment #659); Alexander (Comment #666).

[259] Hua (Comment #45); Campbell (Comment #348).

[260] 69 FR at 40504; 69 FR at 5443.

[261] 69 FR at 40504.

[262] *See, e.g.,* Williford (Comment #38); Glavine (Comment #62); Jones (Comment #63); Copeland (Comment #73); Weinberg (Comment #87); Moody (Comment #92); Buthod (Comment #81); Kreda (Comment #93); Magee (Comment #95); Voreis (Comment #114); Navarro (Comment #117); Taylor (Comment #120); Dyak (Comment #124); Stewart (Comment #136); Madden (Comment #155); Robertson (Comment #180); Chakuroff (Comment #189); Law (Comment #190); Burruss (Comment #192); Bricker (Comment #195); Stephens (Comment #210); Sadeghian (Comment #242); Pentecost (Comment #268); Shaw (Comment #339); Chea (Comment #352); Steinleitner (Comment #517); Holler (Comment #553); Song (Comment #654).

[263] Comment #582 (emphasis deleted). The survey, conducted on behalf of Johnson & Johnson Vision Care, Inc. included 500 contact lens users 18 years of age or older who had purchased contacts online in the prior six months. *See also* Coalition for Patient Vision Care Safety (Comment #621) (referencing 2015 APCO Insight Survey).

[264] Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Ellingson (Comment #66); Leach (Comment #257); Chang (Comment #258); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

[265] 15 U.S.C. 7603(e); 16 CFR 315.5(d). *See also* 69 FR at 40502.

[266] 16 CFR 315.5(a).

seller must contain an expiration date in order to satisfy the definition of contact lens prescription.[267] If the prescription presented to, or in possession of, the seller is expired, that prescription is invalid and the seller cannot use the expired prescription to dispense lenses to the patient. Because the seller has actual knowledge that the prescription is expired, neither may the seller use the expired prescription as the basis for a passive verification request. If, however, a seller has been presented with, or is in possession of, a prescription that does not contain an expiration date, or is otherwise relying on prescription information provided by the patient, then the seller may proceed to verify such prescription with the prescriber.[268] In this latter instance, the seller does not have any knowledge as to whether or not the prescription is expired, and can rely on the prescriber to alert the seller if the prescription is expired.

Other commenters, recognizing that selling contact lenses on an expired prescription is not allowed by the Rule, instead urged the Commission to increase enforcement.[269] The Commission believes that the clarification regarding expired prescriptions as set forth in this document will assist sellers in understanding their obligations under the Rule. In addition, if the Commission receives evidence that sellers are dispensing contact lenses based on expired prescriptions, the Commission will investigate such allegations, as appropriate.

Other commenters explained that because of flaws in the passive verification system sellers ''can request verification of an otherwise expired prescription and can ship the lenses if the prescriber does not recognize within eight business hours that the expiration date has passed and inform the seller.'' [270] In its comment, the Contact Lens Association of Ophthalmologists argued that passive verification ''creates a mechanism for renewal of expired prescriptions, which is in the seller's interest, may be in the consumer's immediate interest, but is not in the interest of the consumer's long term ocular health.'' [271]

In its comment, the American Optometric Association noted that ''an expiration date and issue date are required elements of a prescription'' and the FTC ''should require the expiration date or issue date to be provided in prescription verification.'' [272] This commenter argued that this requirement would incentivize sellers to make sure patients know their prescription expiration date when placing orders. The American Optometric Association further explained that because sellers often market to consumers to reorder in the final month or weeks that the prescription is valid, it believes that sellers already know the prescription expiration date.[273] This commenter concluded that by requiring the expiration date or issue date in the verification request, sellers would be aware, and could not deny when they are using an invalid prescription.[274]

The Commission declines to propose that the Rule be modified in this way. Similar proposals were suggested and rejected during the initial rulemaking.[275] As the Commission recognized at that time, there is ''no reason to believe or evidence to suggest that a seller who is attempting to verify a prescription would necessarily have this information.'' [276] Furthermore, the Commission believes that adopting such a proposal might thwart the intent of the Act. For example, although prescribers themselves have the prescription expiration information because they issued the prescription, a seller verifying a prescription—as opposed to a seller who has a copy of a prescription with an expiration date—may not have access to this information. Because a verification request that does not contain all the required information is not a valid verification request,[277] sellers without expiration information would be at a disadvantage in that they would not be able to verify patient prescriptions based on Section 315.5(c)(3). Furthermore, as noted, prescribers are already in possession of the expiration date, and it is in their economic and professional interest to check the prescriptions and respond to verification requests by informing the seller whenever a prescription has expired.[278]

For the same reasons, the Commission declines to propose to amend the Rule to reflect the American Optometric Association's proposal ''to ban sellers from marketing to specific customers to reorder their lenses after the prescription has expired (more than one year after the issue date or when the customer originally ordered lenses from the seller) unless the seller has specific knowledge the customer's prescription is valid for more than one year.'' [279] To the extent a patient does not have a valid prescription, the Rule already prohibits the sale of contact lenses. However, nothing in the Act supports the extension of this prohibition to the marketing (as opposed to the sale) of contact lenses. It may be in the patient's best interest to receive a reminder to reorder lenses. If the patient does not have a valid prescription, the seller is prohibited from selling the lenses. However, if the patient has visited a prescriber in the interim, the patient will have a valid prescription and the sale can be made.

3. Quantities of Contact Lenses Obtained by Patients

Many commenters expressed the concern that because of inadequacies in the Rule or lack of enforcement, consumers are able to obtain more than a year's supply of contact lenses.[280] For example, some commenters asserted that this occurs because some contact lens retailers allow patients to purchase

[267] 16 CFR 315.2.

[268] 16 CFR 315.5(a)(2).

[269] *See, e.g.,* Peterson (Comment #222); Smith (Comment #319); Heuer (Comment #467); Santarias (Comment #471); Johnson & Johnson Vision Care, Inc. (Comment #582) (''critical to ensure patients continue to see their eye care professionals for their annual check-up and prescription renewal by upholding and enforcing the one-year contact lens prescription expiration date''); Coalition for Patient Vision Care Safety (Comment #621).

[270] American Optometric Association (Comment #644). *See also* Stewart (Comment #136) (stating that expired prescriptions have been filled for years because there was no reply to passive verification).

[271] Comment #572. *See also* American Optometric Association (Comment #644) (''[a]llowing repurchases based on long-expired prescriptions may be, at the time, convenient for the patient and profitable for the seller, but increases the risk of patient harm'').

[272] American Optometric Association (Comment #644).

[273] *Id.*

[274] *Id.*

[275] A state optometry association requested that the Rule be amended to require the verification request to contain the prescription's expiration date as well as the number of refills prescribed. 69 FR at 40496.

[276] *Id.*

[277] *Id.* (''The Commission emphasizes that the sale of contact lenses based on a verification request which does not contain all of the required information constitutes a Rule violation.'').

[278] *See* ''Fairness to Contact Lens Consumers Act: Hearing Before the Subcommittee on Commerce, Trade, and Consumer Protection of the House Committee on Energy and Commerce,'' 108th Cong. 1 (Sept. 12, 2003) (Testimony of Howard Beales, Federal Trade Commission) (noting that passive verification is ''in many respects self-enforcing'').

[279] American Optometric Association (Comment #644).

[280] *See, e.g.,* Rohleder (Comment #57) (''Because of lack of enforcement, patients are able to purchase more contact lenses than they can use in a year, thus allowing them to circumvent seeing their doctor almost indefinitely.''); Filandro (Comment #129) (''A patient can order ten years' worth of contacts and can't be stopped by the law. A patient can order one years' [sic] worth of contacts from ten different vendors and can't be stopped by the law.''); Stewart (Comment #136) (''Patients are able to purchase multi-years [sic] worth of contact lenses even though the prescription clearly states expires in one year.''); Tjandera (Comment #502) (noting that the Rule can be evaded because patients can order from multiple online retailers before the prescription expires).

more than a year's supply of contact lenses,[281] while other prescribers reported that patients are able to refill their contact lenses prescription and obtain more lenses just prior to the prescription expiring.[282] Prescribers also were concerned that they were receiving verification requests from sellers for contact lenses just as the patient's prescription was expiring.[283] A number of commenters complained that contact lens sellers are actively encouraging patients to refill their prescriptions right before they expire.[284] For example, one commenter reported that sellers ''send reminders to patients about a month before their contact lens prescription is expired, to buy another whole year's prescription.'' [285] One contact lens manufacturer reported that an online survey that it had commissioned showed that 58% of the online consumers that were surveyed indicated that they had received an email or letter from their retailer reminding them that their prescription was expiring soon and that the majority of these consumers had ordered more lenses as a result.[286] Other commenters noted that patients are able to obtain more than a year's supply of contact lenses by ordering from multiple sources.[287]

As explained by other commenters, if patients can obtain lenses in excess of a year's supply, expiration dates on prescriptions become meaningless [288] and patients do not return to their eye care professional on an annual basis.[289] Some prescribers provided anecdotal reports of patients not returning for an annual eye exam, sometimes for several years, because they had been able to purchase contact lenses online.[290]

To address these concerns, a number of commenters—optometric and ophthalmologic associations, individual prescribers, and contact lens manufacturers—proposed that the Commission amend the Rule to require contact lens prescriptions to include a maximum quantity of lenses that consumers can purchase prior to the prescription's expiration.[291] These commenters asserted that including a quantity limit on prescriptions would be beneficial to patients' health and safety.[292] One contact lens manufacturer stated that quantity limits ''impose important safeguards and also strengthen the prescriber-patient relationship,'' arguing that if a patient runs out of contact lenses, this would ''offer[] yet another opportunity for consumers to ask questions, share health and other issues they may be encountering with their lenses, or adjust their prescription under the supervision of an eye care professional.'' [293]

In addition to including the maximum quantity on the prescription itself, several state optometric associations also recommended that the Commission ''limit the number of contact lens boxes that can be purchased from a retailer at one time.'' [294] Similarly, the Coalition for Patient Vision Care Safety proposed that the Commission ''forbid retailers to sell in a single transaction a quantity of contact lenses that exceeds a single year's supply.'' [295] As an alternative, the Coalition suggested the Commission require that sellers only provide a supply equal to the length of the underlying prescription.[296] A few commenters stated that because passive verification might allow the consumer to obtain more lenses than medically prescribed, quantity limits should be considered.[297]

A number of commenters argued that contact lens prescriptions should be

[281] Young (Comment #91); Anklin (Comment #107); American Optometric Association (Comment #644).

[282] Day (Comment #4); Driesen (Comment #47); Schwartz (Comment #80); Magee (Comment #95); Johnson (Comment #109); Rosemore (Comment #468); Garcia (Comment #511). *See also* Milsky (Comment #559) (''Another common concern among prescribers is, for example, a prescription for a year's supply of contact lenses getting filled one month before it expires, eleven months after the exam and fitting.'').

[283] Shin (Comment #70); Young (Comment #91); Chakuroff (Comment #189); Koury (Comment #573).

[284] Mathai (Comment #33) (''1800 contacts and other retailers prompt their customers to purchase an annual supply right before their prescription expires so they can save a trip to their Dr [sic] office.''); Jones (Comment #83) (''Contact lens suppliers are actively targeting patients to get them to order outside the limits of the prescription and/or fishing for patient information.''); Young (Comment #91) (''Some online retailers are actively marketing to consumers to purchase more contact lenses when their prescription is 'about to expire'.''); Nelson (Comment #130) (''1–800 Contacts also will not respect a number of refills on the Rx. Instead, they will email the patient before their Rx expires and tell them to order more. Patients then order another year of contacts and then cancel their yearly examination.''); Hans (Comment #168) (patients prompted to save trip to doctor's office); Ellenberger (Comment #272) (same); Gandy (Comment #530) (stop sellers from aggressive and unethical practice of encouraging patients to buy another years' supply of lenses right before their prescription expires); Tass (Comment #586) (same).

[285] Combs (Comment #90).

[286] Johnson & Johnson Vision Care, Inc. (Comment #582) (''nearly six-in-ten online consumers say they have received an email or letter from their retailer reminding them their Rx was expiring soon (58%) and the vast majority who received this notice (86%) ordered more contacts as a result'').

[287] Jones (Comment #83); Filandro (Comment #129); Heuer (Comment #467); Endry (Comment #552); Milsky (Comment #559).

[288] Mirkin (Comment #111); Endry (Comment #552). *See also* Harris (Comment #490) (purchasing contacts right before the prescription expires defeats the purpose of annual expiration dates and the monitoring of patient eye health).

[289] *See, e.g.,* Rohleder (Comment #57); Buthod (Comment #81); Moody (Comment #92); Anklin (Comment #107); Nett (Comment #449); Lisenby (Comment #662).

[290] *See, e.g.,* Weissman (Comment #50) (five years); Grace (Comment #64) (several years); Buthod (Comment #81) (3–5 years); Patel (Comment #188) (companies filling prescriptions for 10 years without successful verification); Pentecost (Comment #268); Silani (Comment #270) (returning for an exam ''years'' later); Chea (Comment #352); Arthur (Comment #371) (five years); Hornberger (Comment #457) (as many as five years); Pickering (Comment #475) (four to five years); Born (Comment #570) (many years); Gronquist (Comment #630) (years).

[291] American Optometric Association (Comment #644); American Academy of Optometry (Comment #623); Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595); Coalition for Patient Vision Care Safety (Comment #621); Stahl (Comment #19); Lum (Comment #21); Peterson (Comment #22); Maanum (Comment #23); Matthews (Comment #25); Borsky (Comment #26); Chriqui (Comment #31); Hodes (Comment #42); Dodge (Comment #44); Kapoor (Comment #58); Comer (Comment #221); Leach (Comment #257); Chang (Comment #258); Whang (Comment #355); Knight (Comment #360); Senator Perdue (Comment #569); Reed (Comment #579); Johnson & Johnson Vision Care, Inc. (Comment #582); Leung (Comment #607); Wu (Comment #608); Vidulich (Comment #612); Lai (Comment #620); Pechko (Comment #628); Liu (Comment #656); Louie (Comment #657); Fong (Comment #669); Vo (Comment #673).

[292] *See, e.g.,* American Optometric Association (Comment #644).

[293] Johnson & Johnson Vision Care, Inc. (Comment #582).

[294] Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

[295] Comment #621.

[296] *Id. See also* Dierks (Comment #32); Ellingson (Comment #66); Moody (Comment #92); Bhadra (Comment #105); Rana (Comment #139); Patel (Comment #237); Santry (Comment #529).

[297] Wilson (Comment #76) (passive verification allows the contact lens seller to sell the patients more lenses than are medically prescribed); Kline (Comment #161) (same); Johnson & Johnson Vision Care, Inc. (Comment #582).

treated the same way as pharmaceutical prescriptions in order to prevent the dispensing of excess quantities.[298] As described by one commenter, this would require the quantity to be included on the prescription and the retention of the prescription by the dispenser filling it.[299] A few commenters suggested a pro rata approach. For example, one prescriber recommended that consumers should only be able to obtain refills commensurate with the amount of time left on the prescription.[300] Likewise, the Coalition for Patient Vision Safety proposed a similar approach, suggesting that the Commission ''restrict the sale of contact lenses on a prescription that is nine months after issuance or older to up to 25 percent of the prescription's course.'' [301] One contact lens manufacturer recommended that the Commission modify the Rule to ''place[] reasonable limits on the quantity of contact lenses a patient can purchase under a prescription (especially within a few months of a prescription expiring)'' in order to encourage patients to go to their eye care professional for routine examinations.[302]

However, other commenters disagreed with the proposal to include quantity limits on contact lens prescriptions. 1–800 CONTACTS argued that imposing quantity limits would ''inconvenience consumers and lead to unhealthy practices, such as wearing lenses longer than recommended.'' [303] This commenter asserted that patients could misplace or tear lenses, or might replace their lenses more frequently than anticipated by their prescription, and consequently concluded that ''there are any number of very legitimate reasons a consumer may want to purchase what appear to be (based on simple multiplication) extra lenses and there is no valid reason to restrict that consumer's options.'' [304]

Another contact lens retailer claimed that prescribers were circumventing the minimum one-year expiration period by ''limit[ing] the quantity of replacement lenses, despite the lack of any medical reason for ever doing so'' and that ''a consumer's need for additional lenses could arise for a number of reasons.'' [305] This commenter proposed that the Commission amend Section 315.6 of the Rule to include a provision stating that a ''contact lens prescription shall be valid for an unlimited quantity of lenses regardless of any prescriber-imposed limitation to the contrary.'' [306]

After reviewing the comments, the Commission has determined not to propose to amend the Rule to adopt any of the contact lens quantity proposals put forth by commenters. First, the Commission does not believe that there is sufficient evidence in the rulemaking record to support amending the Rule to impose the quantity limit proposals suggested by commenters. Although some commenters conducted and submitted data from online surveys for the proposition that consumers are purchasing contact lenses as their prescriptions are about to expire, this data does not show the quantity of lenses that consumers are actually purchasing. For example, even if one were to assume that the APCO online survey results were completely reliable, the survey only asked consumers whether they purchased lenses at certain points in time; it did not assess the quantity of lenses that consumers actually purchased. The fact that a consumer purchased some contact lenses just prior to a prescription expiring does not necessarily mean that the consumer has purchased an excessive amount of contact lenses, nor does it support the contention that consumers are no longer getting eye examinations. Instead, consumers could be purchasing small amounts of lenses to last until their next scheduled eye examination. When the Commission examined the contact lens industry in 2005, it found that consumers do not typically purchase a full year's supply at one time.[307] The Commission has not seen any evidence indicating that this has changed. Although commenters to the current Rule review provided various anecdotal and hypothetical accounts of consumers buying excessive quantities of lenses, they did not provide empirical evidence regarding the amount of lenses consumers are obtaining, nor did they submit evidence to show that consumers are not visiting their eye care practitioners as frequently.[308] Second, regardless of the evidence, or lack thereof, in the record to support the quantity limit proposals, the Commission believes that it would be difficult to administer the proposed limits, and that rather than increasing patient eye health and safety, such proposals could have the opposite effect. For example, if a consumer is running out of contact lenses and does not have time to see a prescriber promptly, there is a significant chance that the consumer will not adhere to the recommended contact lens replacement schedule and will instead try to ''stretch out'' their lenses by re-wearing them until they can visit a prescriber. The failure to replace lenses is a well-documented cause of many contact-lens-related health issues.[309] Absent empirical evidence that a substantial number of consumers are obtaining excessive amounts of contact lenses, or are not returning to their prescribers for eye examinations, the Commission believes that the risk of not replacing lenses outweighs the harm of consumers obtaining more lenses than strictly anticipated by the length of a contact lens prescription.

Nevertheless, the Commission is concerned about anecdotal reports that sellers are contacting patients and encouraging them to stockpile contact lenses prior to the expiration of their prescriptions in order to avoid visiting their eye care professionals. The Commission cautions sellers that such practices run counter to the spirit of the Act, and the Commission will look closely at these alleged practices.

The Commission also declines to propose that the Rule be amended to provide that a ''contact lens prescription shall be valid for an unlimited quantity of lenses regardless of any prescriber-imposed limitation to the contrary.'' [310] The commenter suggesting this amendment produced no evidence supporting the allegation that prescribers are using quantity limits to undercut the length of a prescription.

The Commission also notes that, as recognized during the initial rulemaking, some State laws or regulations may require prescribers to include quantity information on the prescription and some prescribers in other States without such requirements

[298] *See, e.g.,* Filandro (Comment #129); Kalman (Comment #150); Bainbridge (Comment #152); Anderson (Comment #185); Palermo (Comment #212); Sanders (Comment #235); Sanders (Comment #236); Smith (Comment #319); Chesen (Comment #350); Perichak (Comment #415); Witmeyer (Comment #418); Palmer (Comment #484); Pierzchala (Comment #500); Haefs (Comment #525); Johnson & Johnson Vision Care, Inc. (Comment #582); Tass (Comment #586); Ball (Comment #590); Alexander (Comment #666).

[299] Kalman (Comment #150).

[300] *See, e.g.,* Milsky (Comment #559).

[301] Comment #621.

[302] CooperVision, Inc. (Comment #591).

[303] Comment #568.

[304] *Id.*

[305] LD Vision Group (Comment #544).

[306] *Id.*

[307] 2005 Contact Lens Report, *supra* note 14, at 6 note 18 (citing two studies that found that just 12–20% of consumers purchase a year's supply at a time).

[308] Indeed, the Coalition for Patient Vision Care Safety indicated that ''87 percent of contact lens patients had an eye exam last year.'' Comment #621.

[309] Cope, *supra* note 29, at 867 (''contact lens wearers who do not follow recommended contact lens replacement schedules have more complications and eye discomfort'').

[310] LD Vision Group (Comment #544).

may choose to include such information on the prescription. At this time, the Commission reiterates that such prescribers must not use quantity limits to frustrate the prescription expiration requirements of Section 315.6, and that the quantity specified in the prescription must be sufficient to last through the prescription's expiration date.[311]

Finally, the Commission also believes that the Rule, as currently drafted, is sufficient to address the quantity limit concerns posited by commenters. During the initial rulemaking, the Commission examined the issue of requiring quantity limits on prescriptions.[312] At that time, the Commission concluded that it was not necessary to include the quantity of lenses on the prescription to limit patients' ability to circumvent the expiration date because the verification process would allow prescribers to prevent patients from ordering excessive contact lenses.[313] In this rule review, commenters raised concerns that the verification process was not an adequate safety net because the ''verification process is not triggered when a patient provides a contact lens retailer with a complete copy of prescription'' and the verification process is bypassed.[314] Accordingly, it is possible that consumers could use a copy of a prescription to shop at multiple retailers, or engage in other practices, in order to obtain excessive amounts of contact lenses.[315] Although it is possible that these practices could occur, there is no empirical evidence in the record to show the frequency or extent of such practices.[316]

Other commenters encouraged the Commission to increase enforcement efforts to prevent consumers from obtaining more contact lenses than anticipated by the length of the prescription.[317] As already noted, if the Commission receives evidence that sellers are dispensing contact lenses in violation of the Rule, the Commission will investigate such allegations, as appropriate.

B. Private Label Lenses and Contact Lens Substitution

1. Private Label Lenses

A few sellers commented on the Rule provision regarding private label lenses.[318] Section 315.2 of the Rule defines private label contact lenses as ''contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.'' [319] A prescription for private label contact lenses, in addition to other required information, must include the name of the manufacturer, trade name of the private label brand, and if applicable, trade name of equivalent brand name.[320] The Rule's requirements for private label lens prescriptions track the language of the Act.[321] Although most contact lenses are sold under their national brand name, some manufacturers also distribute their lenses to prescribers and retailers under private labels. Sometimes the private label is unique to that seller and other times the private label brand may be available at multiple outlets.[322]

LD Vision Group, an online contact lens retailer, asserted that manufacturers and prescribers design anticompetitive strategies involving private label lenses to ''thwart consumer freedom.'' [323] Specifically, the company contended that to keep consumers from purchasing contacts elsewhere, some prescribers ''will provide unpopular or private-label lenses without published equivalents or for which the equivalents are confusing.'' [324] For instance, the company stated that one private label ''is purportedly available with an 8.3 or 8.6 base curve, while the brand name lens—though it is the exact same lens—is purportedly available with an 8.4 or 8.7 base curve.'' [325] Another manufacturer, according to LD Vision Group, ''offers four different lenses under a private label: Standard, plus, premium, and premium plus, but the national-label equivalents do not use the same identifiers.'' [326] Although prescribers are required by the Rule to list equivalent information on the prescription, LD Vision Group asserted that prescribers do not always comply, and absent manufacturers' identification of equivalent lenses, ''the retailer must either refuse to dispense unknown equivalents or make assumptions based on intentionally misleading private-label designations and risk dispensing the wrong lenses to the potential detriment of their customers' eye health.'' [327] LD Vision Group did not quantify the extent of this problem, or provide empirical evidence as to its scope.[328]

In order to remedy the aforementioned issues, LD Vision Group proposed that the Commission amend the Rule to require prescribers to annotate a private label lens prescription with the brand-name equivalent and, if a name-brand equivalent is unavailable, the private label prescription must be medically necessary for that particular patient. It also recommended requiring manufacturers of contact lenses to disclose brand equivalency information on private label and brand-label packaging, or otherwise make it available to sellers.[329]

The Commission declines to propose to modify the Rule to implement these recommendations. Although the Act expressly requires that, in the case of private label contact lens prescriptions, prescribers include ''trade name of equivalent brand name,'' the Act does

[311] 69 FR at 40488. If the prescription specifies a lesser quantity of lenses or refills, the prescriber must have a legitimate medical reason for doing so, and the requirements imposed by Section 315.6(b) on writing a prescription for less than one year must be met. *Id.*

[312] In reaching that determination, the Commission first noted that the Act did not require the inclusion of quantity information on the prescription. The Commission then discussed its concern that if quantity information was included, prescribers might use those quantity limits to impose prescription expiration dates that are effectively shorter than the one-year period imposed under the Act. 69 FR at 40488.

[313] 69 FR at 40488 (explaining that Section 315.5(b) requires verification requests to contain the quantity of lenses ordered, and that the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification of a prescription as ''inaccurate'').

[314] American Optometric Association (Comment #644). *See also* Coalition for Patient Vision Care Safety (Comment #621).

[315] *Id.*

[316] For the same reasons, the Commission also declines to propose to amend the Rule per the American Optometric Association's proposal that the Commission limit the quantity of contact lens boxes that retailers advertise as being able to be purchased at one time. Comment #644. In its comment, the American Optometric Association contended that it is possible that consumers could purchase large amounts of contact lenses from some online retailers; however, it did not provide support for this contention.

[317] *See, e.g.,* Day (Comment #4); Mathai (Comment #33); Nelson (Comment #130); Hans (Comment #168); Garcia (Comment #511); Gandy (Comment #530); Tass (Comment #586).

[318] LD Vision Group (Comment #544); 1–800 CONTACTS (Comment #568).

[319] 16 CFR 315.2.

[320] *Id.*

[321] *See* 15 U.S.C. 7610(3).

[322] 2005 Contact Lens Report, *supra* note 14, at 14–15.

[323] Comment #544. LD Vision Group explained that manufacturers acquiesce to prescribers because it is the prescribers who select their patients' contact lenses. *Id.; see also* 1–800 CONTACTS (Comment #568) (commenting on manufacturers' strong incentives to cater to the interests of prescribers rather than consumers because prescribers determine the brand and modality of their patients' lenses).

[324] Comment #544.

[325] LD Vision Group did not identify the private label or manufacturer engaged in this practice. Comment #544.

[326] *Id.*

[327] As discussed in Section V.B.2, *infra,* when sellers substitute lenses that are not identical to the prescribed contact lenses, they violate the Rule.

[328] The Commission understands that sales of private label lenses comprise a small part of the market, and most major manufacturers do not sell private label lenses.

[329] LD Vision Group (Comment #544).

not impose a requirement of medical necessity in order for a prescriber to prescribe a private label lens for which no name-brand equivalent exists.[330] Nor does the Act expressly contemplate the imposition of disclosure requirements on manufacturers. However, nothing in the Act or Rule prohibits manufacturers from making brand equivalency disclosures on their packaging, or otherwise making such information available to sellers. The Commission understands that some, if not all, manufacturers who offer private labels already make this information readily available to retailers. Additionally, the Commission notes that it is a violation of the Rule for prescribers to fail to comply with their obligation to specify a brand equivalent, should one exist, when writing a prescription. The Commission encourages sellers and consumers to submit evidence of any such violations to the agency for possible enforcement action.

2. Alteration of Contact Lens Prescriptions by Sellers

Section 315.5(e) of the Rule prohibits sellers from altering a contact lens prescription.[331] Notwithstanding this prohibition, a seller may substitute for private label contact lenses specified on a prescription, ''identical contact lenses that the same company manufactures and sells under different labels.'' [332] The language of this Rule provision is substantively the same as the language of the Act, with one exception discussed below.[333]

The Commission received a number of comments, primarily from prescribers, that complained that online contact lens sellers are selling patients lenses different from those they prescribed.[334] Prescribers expressed concern that contact lenses are being treated like commodities, rather than restricted medical devices regulated by the FDA.[335] These commenters contended that contact lenses, even those with similar refractive specifications, are not interchangeable.[336] One commenter, a manufacturer, opined that ''each brand is unique and proprietary to each manufacturer and designed to suit a different set of corresponding patient physiology and consumer needs.'' [337]

Several prescribers and a manufacturer also explained that prescribers work with patients to fit them with the most compatible, safe, and effective contact lens and that each patient's eyes react differently to individual brands.[338] According to these commenters, when a patient receives a contact lens that is not identical to the one prescribed, those lenses have not been fit on the patient, may not be appropriate, and can even be harmful for the patient.[339] Specifically, prescribers stated that scarring, infection, allergic reactions, corneal ulcers, impaired or even lost vision can result or have resulted from patients wearing lenses that were not prescribed.[340] A few prescribers described patients who, after wearing lenses that had not been prescribed for them, could no longer wear contact lenses or whose vision could no longer be fully corrected.[341]

As to the source of the alteration problem, commenters pointed to both online sellers as well as patients. Commenters, almost exclusively prescribers, asserted that sellers want to maximize their profits and may have little to no consideration for their customers' eye health,[342] and that patients switch brands to obtain cheaper lenses or seek brands they have seen in commercials.[343] Some prescribers also stated or implied that these substitutions occur as a result of the passive verification system, and encouraged the Commission to adopt an active verification system.[344]

It is unclear how frequently illegal substitutions are occurring, or how many sellers are engaged in this activity. In its comment, Johnson & Johnson Vision Care, Inc. cited to a 2015 online survey conducted on its behalf that found that ''one-in-four online consumers report having received a different brand of contact lenses than they had ordered without being given advanced warning they were getting another brand.'' [345] Even assuming the survey methodology is sound and the stated conclusion of the survey is accurate, it is not clear whether the positive responses reflect instances

[330] In the initial rulemaking, sellers made a recommendation to open up the market by requiring prescribers, when prescribing private label contact lenses, to identify on the prescription the name of a brand that a consumer could purchase from a retailer other than the prescribing office. 69 FR at 40503. The Act does not limit, in any way, the brand that a prescriber must select and thus, the Commission concluded that such a requirement would go beyond the Act. *Id.* LD Vision Group's similar proposal to limit prescribers from prescribing private label brands without a brand-equivalent, except in the case of medical necessity, fails for the same reason.

[331] 16 CFR 315.5(e).

[332] *Id.*

[333] *See* 15 U.S.C. 7603(f).

[334] *See, e.g.,* Kapoor (Comment #58); Narayan (Comment #60); Thomas (Comment #61); Weinberg (Comment #87); Anderson (Comment #96); Hopkins (Comment #102); Johnson (Comment #109); O'Brien (Comment #127); Stewart (Comment #136); Hans (Comment #168); Hamilton (Comment #216); Gibson (Comment #217); Cassis (Comment #233); Chesen (Comment #321); Silver (Comment #349); McWilliams (Comment #362); Wittmann (Comment #421); Nett (Comment #449); Eggers (Comment #473); Kegarise (Comment #477); Kosunick (Comment #501); Wren (Comment #520); Lai (Comment #541); Hamada (Comment #603); Coalition for Patient Vision Care Safety (Comment #621); Maceyko (Comment #642); American Optometric Association (Comment #644).

[335] Kelly (Comment #78); Callihan (Comment #187); Sancho (Comment #226); West (Comment #230); Nett (Comment #449); Vu (Comment #561); Reed (Comment #579). *Cf.* LD Vision Group (Comment #544) (calling lenses a ''disposable commodity'').

[336] *See, e.g.,* Johnson & Johnson Vision Care, Inc. (Comment #582) (citing studies supporting this statement). A number of commenters similarly explained that because each contact lens fits the eye differently, there is no such thing as a generic contact lens. *See, e.g.,* Jones (Comment #63); Miyamura (Comment #77); Jones (Comment #83); Easton (Comment #432).

[337] Comment #582. Johnson & Johnson Vision Care, Inc. described several parameters that make a contact lens brand unique, including oxygen transmissibility, water content, iconicity, rigidity or modulus, silicone and fluorine content, lipid deposition, wettability/wetting agent, thickness, diameter, base curve, edge design, surface characteristics/treatments, modality, UV blocking, and interaction with care solutions. Other commenters mentioned modality (daily, two week replacement, or monthly), optical clarity, lifestyle, medical conditions, and current medications as factors influencing the prescriber's selection of the contact lens to prescribe. Morgan (Comment #144); Assell (Comment #397).

[338] *See* Sasner (Comment #182); Williams (Comment #261); Steinleitner (Comment #517); Nielson (Comment #565) (prescriber questioning why he learned how to fit contact lenses if patients can get any lens they want without his input); Johnson & Johnson Vision Care, Inc. (Comment #582).

[339] *Id.*

[340] Williford (Comment #38); Kapoor (Comment #58); Jones (Comment #63); Morgan (Comment #144); Herve (Comment #148); Sausner (Comment #182); McWilliams (Comment #362); Elmore (Comment #396); Wittmann (Comment #421); Kegarise (Comment #447); Sirotkin (Comment #464); Abbott (Comment #497); Wren (Comment #520); Evans (Comment #523); Hamada (Comment #603); Capps (Comment #610); Coalition for Patient Vision Care Safety (Comment #621); Vehab (Comment #622); Mortenson (Comment #636); Maceyko (Comment #642).

[341] Schram (Comment #184); McWilliams (Comment #362).

[342] Nguyen (Comment #82); Eggers (Comment #473); Lupinski (Comment #499); Nielsen (Comment #565). Other prescribers are concerned that they will be liable or at risk of losing their licenses if the substitution causes the consumer harm. *See, e.g.,* Carroll (Comment #5); Thomas (Comment #61).

[343] LaDouceur (Comment #178); Schram (Comment #184); Marler (Comment #504); Vehab (Comment #622).

[344] Prescribers contend that after sellers convince patients to order different lenses than those prescribed, or patients give sellers the name of a lens not identical to the prescribed lens, the sellers send a verification request containing the non-prescribed lenses, and those requests are sometimes passively verified. Eggers (Comment #473); Wren (Comment #520). As previously explained, *see supra* Section IV.C.1, the Commission lacks authority to eliminate the passive verification system.

[345] Comment #582.

when sellers made illegal alterations or, alternatively, instances when consumers ordered a brand other than the prescribed brand and the prescribers then corrected the prescriptions. Nor is it clear whether positive responses include instances where eye care professionals prescribed private label lenses and sellers appropriately substituted them with identical lenses, made by the same manufacturer and sold under a different label, as expressly permitted by Section 315.5(e). Because one cannot tell the percentage that was the result of unauthorized alterations, the survey data is not conclusive.[346]

The Commission notes that unauthorized alterations violate the Rule as currently written, and thus there is no need to amend the Rule to address this issue.[347] In some cases, patients may request to purchase a brand of lenses not identical to the one prescribed. In those instances, the seller may include the wrong brand in the verification request. If any of the information required by Section 315.5(b)(2) to be included in the verification request is incorrect, prescribers are encouraged to provide the correct information to the seller.

Several commenters requested that the Commission better enforce the Rule against sellers that engage in illegal substitutions.[348] If the Commission receives evidence that sellers are engaged in illegal substitutions, the Commission will investigate the allegations, as appropriate.[349]

Lastly, one commenter, an optometrist, recommended that a retailer should be required to warn or educate patients about the potential consequences of changing brands or other parameters without a doctor's authorization through a ''statement of education'' with every order, warning patients that ''contact lenses are a medical device and the wearing of or changing of a brand or prescription without a doctor's authorization is illegal and could result in damage, even blindness to the recipient.'' [350] The Commission declines to modify the Rule in such a fashion. Although the Commission does not take issue with the importance of educating patients about the need to consult their prescriber before switching contact lens brands, and encourages sellers, prescribers, and manufacturers to do so, we have no evidence that the benefit of imposing such a requirement on sellers would outweigh the costs.

Through discussions with industry members, it has come to the Commission's attention that in addition to prescribers, some other sellers market and sell private label contact lenses that are identical to, and are made by the same manufacturer as, brand name contact lenses. As a result, when a patient presents a contact lens prescription for brand name contact lenses to certain sellers, those sellers may wish to sell, as a substitute, their own private label lenses to the patient. The language of the Act clearly permits substitution in cases where the same contact lenses are manufactured by the same company and sold under multiple labels to individual providers.[351] Although the Rule similarly permits a seller to substitute lenses that are identical to, and are made by the same manufacturer as, the one listed on the prescription,[352] the language set forth in Section 315.5(e) of the Rule could be read to limit such substitution to instances where private label lenses are listed on the prescription and the seller wishes to substitute brand name lenses.[353]

The Commission recognizes that the current construction of Section 315.5(e) of the Rule does not conform to the language or intent of the Act. The clear language of the Act allows sellers to substitute private label lenses for brand name lenses when the substituted lenses are ''manufactured by the same company and sold under multiple labels to individual providers.'' [354] To conform the Rule to the Act, the Commission proposes to strike the words ''private label'' from Section 315.5(e) and seeks comment on its proposal. The definitions in the Rule of a ''contact lens prescription'' and of a ''private label contact lens'' would remain unchanged.

C. HIPAA Issues

The Commission received a few comments that identified concerns with how the Rule's verification framework interacts with the Health Insurance Portability and Accountability Act of 1996 [355] (''HIPAA'') Privacy and Security Rules (''HIPAA Rules'').[356] One prescriber expressed the opinion that the Contact Lens Rule's verification system was in direct conflict with HIPAA and detailed his attempts to procure HIPAA authorizations from his patients prior to releasing the prescription to a third-party seller.[357] Another commenter recommended that HIPAA should apply to the verification process and that any verification request should be accompanied by an authorization signed by the patient.[358] A third commenter expressed concern that automated telephonic verification requests were in direct violation of HIPAA because the patient's personal information was relayed to the person answering the telephone, without any mechanism to ensure that it was the intended recipient.[359] A few prescribers also complained that sellers' practices of trying to obtain prescriptions without patient authorization violated HIPAA.[360]

Other commenters stated that some prescribers were not complying with the Contact Lens Rule and were using HIPAA to avoid doing so. One seller complained that ''[s]ome prescribers will still refuse to verify even with the law in place, stating (incorrectly) that HIPAA or a state privacy rule prohibits

[346] Other seemingly relevant survey questions, one of which a commenter cited to, may be similarly flawed. For example, the Coalition for Patient Vision Care Safety pointed out that 31% of respondents answered positively when asked: ''When buying contact lenses online or over the phone in the past, has the company you were ordering from ever informed you that they do not carry or do not currently have stocked, the brand of contact lenses on your prescription, and advised you to get another brand of contact lenses instead?'' Comment #621. In response to a subsequent survey question, 80% of those respondents indicated that they ''then order[ed] that other brand of contact lenses.'' The Commission notes that positive responses to these questions do not necessarily reflect a violation of the Rule. For example, a prescriber changing a prescription to a different lens in the interim would thereby render the sale proper.

[347] Because prescription alteration violates the Rule, the Commission need not make its own assessment of Johnson & Johnson Vision Care, Inc.'s and numerous prescribers' statements concerning the non-interchangeability of lenses and the resulting eye health risks.

[348] Thomas (Comment #61); Lai (Comment #541); Johnson & Johnson Vision Care, Inc. (Comment #582).

[349] The Commission notes that the prescriber has the ability to block an illegal substitution by actively responding to a verification request for a non-prescribed lens and indicating its invalidity. In fact, in circumstances where a consumer selects a non-prescribed brand, the prescriber is likely the only one who can ''catch'' the error.

[350] Kegarise (Comment #447).

[351] 15 U.S.C. 7603(f).

[352] 16 CFR 315.5(e).

[353] Section 315.5(e) modifies ''contact lenses'' with the term ''private label,'' but the Act does not contain that modifier. *Cf.* 15 U.S.C. 7603(f).

[354] 15 U.S.C. 7603(f). Although the Commission imagines it would be quite rare, it believes a seller should be permitted under the Rule to substitute one private label lens for another private label lens as long as the lenses are identical.

[355] Public Law 104–191 (Aug. 21, 1996).

[356] 45 CFR parts 160, 164.

[357] Ciszek (Comment #134).

[358] Pao (Comment #181).

[359] Stuart (Comment #635) (consumers' ''personal and medical information is currently being transmitted unsecured to a third party by using an automated phone verification system'').

[360] St. Martin (Comment #292) (''their phishing for prescriptions should be considered a HIPAA violation because often this is done without the patient's permission''). *See also* Vensand (Comment #59) (expressing concern about the acquisition and sale of patient information); Ciszek (Comment #134) (complaining that sellers are calling of their own accord, without the patient initiating the request).

release of the prescription and that only the patient can ask for it.'' [361] Likewise, the National Association of Optometrists and Opticians noted that it was ''aware of instances where prescribers incorrectly inform patients that HIPAA or other laws require a written authorization from the patient or face-to-face requests by the patient to the prescriber.'' [362] This commenter recommended that the Commission make clear to prescribers, sellers, and consumers that HIPAA does not prevent compliance with the Rule's verification process and that to claim otherwise is an unfair and deceptive practice.[363]

The Commission reiterates that the HIPAA Privacy Rule does not restrict prescribers' ability to provide or verify contact lens prescriptions under the Rule.[364] As a preliminary matter, HIPAA does not require submission of a HIPAA authorization for the prescriber to release a contact lens prescription to a patient.[365] Furthermore, as the Commission explained in the initial rulemaking, the HIPAA Privacy Rule permits a HIPAA covered entity, such as a covered prescriber, to disclose protected health information (''PHI'') without patient authorization for ''treatment'' purposes or when ''required by law,'' as well as for other specified purposes.[366] Providing, confirming, or correcting a prescription for contact lenses for a contact lens seller as contemplated under the Contact Lens Rule constitutes ''treatment'' under the HIPAA Privacy Rule.[367] In addition, to the extent the disclosure of PHI to provide, confirm, or verify a contact lens prescription is required under the Act and the Rule, such disclosure constitutes a disclosure ''required by law'' under the HIPAA Privacy Rule.[368] For these reasons, patient authorization is not required for a prescriber to provide or verify a contact lens prescription with the contact lens seller, or to provide a contact lens prescription to the patient.[369]

In addition to the comments submitted in this rule review, the Commission has received other questions and complaints related to prescribers' HIPAA obligations under the Rule. For example, one prescriber asked whether HIPAA precluded his office from emailing a copy of a prescription to a patient without written authorization if the email communication was not encrypted. Correspondingly, some consumers have complained that their eye care practitioners have refused to email contact lens prescriptions to them.

As a threshold matter, the Contact Lens Rule itself contemplates email communication, stating that the prescriber shall ''provide or verify'' the prescription ''by electronic or other means.'' [370] Further, the HIPAA Rules do not preclude covered prescribers from emailing contact lens prescriptions to patients or sellers. According to guidance provided by the U.S. Department of Health & Human Services, the HIPAA Rules allow health care providers to communicate electronically with patients, provided they apply reasonable safeguards.[371] Although a covered provider must consider encryption to protect against unintentional disclosures, the provider may determine that it is not reasonable and appropriate, and may instead apply precautions when transmitting unencrypted email, such as checking the email address for accuracy before sending, sending an email alert to the intended recipient for address confirmation prior to sending the message, and limiting the amount and type of PHI transmitted through the email.[372]

Regardless, where an individual requests that the covered entity transmit PHI by unencrypted email, as is their right under the HIPAA Privacy Rule right of access, a covered entity must do so.[373] Before sending unencrypted email containing PHI to a patient, the entity should advise the patient of the risk that the unencrypted PHI could be intercepted and accessed by unauthorized third parties. If, after having been advised of the risks the patient still prefers to receive his or her PHI via unencrypted email, the patient has the right to receive the PHI in that manner and the covered entity is not responsible for unauthorized access to the PHI during electronic transmission, nor is the covered entity responsible for safeguarding the PHI once delivered to the patient.[374] Conversely, a covered prescriber also must honor a patient's reasonable request that the prescriber *not* send communications via unencrypted email, by offering other means, such as encrypted email, secure patient portal, postal mail, or telephone.[375]

D. Enforcement Efforts

In addition to proposing amendments to specific Rule provisions to further the Rule's goals of competition and patient welfare, several commenters also urged the Commission to increase its enforcement efforts and stressed the importance of enforcing the Rule to ensure that its benefits are realized and

[361] LD Vision Group (Comment #544).

[362] Comment #549.

[363] *Id.*

[364] 69 FR at 40501.

[365] *See* 45 CFR 164.502(a)(1); U.S. Dep't of Health & Human Servs., Office for Civil Rights, ''Summary of the HIPAA Privacy Rule'' 4–5 (2003), *http://www.hhs.gov/sites/default/files/privacysummary.pdf* (''A covered entity is permitted . . . to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: (1) To the Individual (unless required for access or accounting of disclosures); (2) Treatment, Payment, and Health Care Operations; (3) Opportunity to Agree or Object; (4) Incident to an otherwise permitted use and disclosure; (5) Public Interest and Benefit Activities; and (6) Limited Data Set for the purposes of research, public health or health care operations. Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.'') (footnote omitted).

[366] 69 FR at 40501.

[367] *Id. See also* Standards for Privacy of Individually Identifiable Health Information, 67 FR 53182, 53219 (Aug. 14, 2002). The U.S. Department of Health & Human Services has explained further that ''disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is a treatment disclosure and is permitted under the Privacy Rule at 45 CFR 164.506.'' *See* U.S. Dep't Health & Human Servs., Health Information Privacy, FAQs, ''Does the HIPAA Privacy Rule permit an eye doctor to confirm a contact prescription received by a mail order contact company?,'' *http://www.hhs.gov/hipaa/for-professionals/faq/270/does-hipaa-permit-an-eye-doctor-to-confirm-a-contract-prescription-from-a-mail-order-company/index.html.*

[368] *See* 45 CFR 164.512(a).

[369] In addition, the HIPAA Privacy Rule right of access requires a covered prescriber to provide to the patient upon request or to another person she designates a copy of a prescription. *See* 45 CFR 164.524(c)(3). *See also* U.S. Dep't Health & Human Servs., Health Information Privacy, HIPAA Guidance, ''Individuals' Right under HIPAA to Access their Health Information,'' *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/.*

[370] 16 CFR 315.3(a)(2).

[371] U.S. Dep't Health & Human Servs., Health Information Privacy, FAQs, ''Does the HIPAA Privacy Rule permit health care providers to use email to discuss health issues and treatment with their patients?,'' *http://www.hhs.gov/hipaa/for-professionals/faq/570/does-hipaa-permit-health-care-providers-to-use-email-to-discuss-health-issues-with-patients/. See also* 45 CFR 164.530(c).

[372] Encryption of PHI must be implemented where a covered entity has determined that it is a reasonable and appropriate safeguard as part of its risk management. *See* U.S. Dep't Health & Human Servs., Health Information Privacy, FAQs, ''Is the use of encryption mandatory in the Security Rule?,'' *http://www.hhs.gov/hipaa/for-professionals/faq/2001/is-the-use-of-encryption-mandatory-in-the-security-rule/index.html.* A covered health care provider also must protect PHI in those emails while they are stored on servers, workstations, mobile devices, and other computer systems, through encryption and other safeguards, as appropriate. *See* 45 CFR 164.306(a).

[373] 45 CFR 164.524(c). *See also* U.S. Dep't Health & Human Servs., Health Information Privacy, FAQs, ''Individuals' Right under HIPAA to Access their Health Information 45 CFR 164.524,'' *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/.*

[374] 78 FR 5634 (Jan. 25, 2013).

[375] 45 CFR 164.522(b).

its risks minimized.[376] For example, several optometric associations urged the Commission to enforce the basic patient safeguards outlined in the Act to protect patients and reduce unnecessary costs.[377] These commenters argued that the sale of contact lenses without a valid prescription increases risks for patients and ultimately leads to higher health costs, and called for the Commission to take action against retailers selling lenses without a valid prescription.[378] The Coalition for Patient Vision Care Safety asserted that ''noncompliance with and loopholes within the law have resulted in a deceptive flow of information to contact lens patients, and have the potential to compromise seriously the vision health of patients.'' [379] Many individual prescribers also urged the Commission generally to increase enforcement of the Rule.[380]

On the other hand, online retailers such as 1–800 CONTACTS and Warby Parker recommended increased enforcement efforts against non-compliant prescribers, particularly with respect to the automatic release of prescriptions.[381] These commenters complained that despite ''the widespread refusal of prescribers to release prescriptions,'' Commission action against prescribers has been limited to a handful of warning letters.[382] These commenters proposed that the Commission amend Section 315.9 of the Rule, the enforcement provision, to add language to clarify that any violation of the Rule—*by either sellers or prescribers*—constitutes a violation of a rule under Section 18 of the Federal Trade Commission Act, subject to the same fines and penalties as any other violation of the Act.[383]

With respect to commenters' recommendations that the Commission increase its enforcement efforts, the Commission notes that the rule review process has been instrumental in identifying areas that need further investigation. Accordingly, the Commission will consider ways to leverage its enforcement, consumer education,[384] and business guidance efforts to address the concerns identified.[385] However, the Commission does not believe it necessary to amend Section 315.9 of the Rule to clarify that violations by either sellers or prescribers constitute a violation of the Rule under Section 18 of the Federal Trade Commission Act. The language of the Act and Rule are clear on this point.[386]

E. Recommendations Regarding the Commission's Complaint Reporting System

The Commission received a variety of comments suggesting proposals to improve perceived shortcomings in the agency's complaint reporting system to aid Rule enforcement efforts. Several optometric associations, for example, expressed their opinion that the Commission's consumer reporting process is not adequately designed to deal with contact lens complaints, and recommended that the Commission ''develop a distinct complaint submission process for contact lens-related concerns.'' [387] More specifically, the American Optometric Association asserted that the online complaint assistant service is not appropriately set up to receive these types of complaints, and doctors who report issues of concern often feel their reports go unnoticed.[388] This commenter stated that setting up a distinct Contact Lens Rule complaint system would benefit patients as well, providing them with a simple process to follow in case they have contact lens sale-related concerns.[389] Likewise, the Coalition for Patient Vision Care Safety was troubled that the agency ''routes eye contact complaints about non-compliance to its general complaint lines'' and asserted that the general routing of complaints discourages the reporting of complaints and fails to provide the Commission with adequate and accessible information to enforce the Rule.[390] The Coalition recommended that the Commission instead utilize dedicated personnel paired with a dedicated Web site or phone number within the Commission.[391]

Other commenters expressed doubts that the complaint reporting system was adequate to capture specific types of complaints. For example, two State representatives, Rhode Island State Rep. Brian Patrick Kennedy and Arizona State Rep. Heather Carter, asserted that the current system favors eye care providers and their ability to file complaints against resellers of contact lenses.[392] These commenters recommended that the Commission consider simplifying the complaint process to make it easier for consumers

[376] *See, e.g.,* Barr (Comment #639).

[377] American Optometric Association (Comment #644); Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595). *See also* American Academy of Ophthalmology (Comment #611) (''Wearing improper lenses can further complicate existing vision issues, including leading to infection in the eye. The sale of lenses without a prescription is a practice that continues despite the Rule, and the Academy believes that the Commission should take swift action to improve enforcement of the Rule.'').

[378] *Id.*

[379] Comment #621.

[380] *See, e.g.,* Filandro (Comment #129); Sandler (Comment #135); Jankowski (Comment #153); Hans (Comment #168); Nguyen (Comment #175); Robertson (Comment #180); Schumacher (Comment #193); Sisson (Comment #254); Frederick (Comment #269); Bolenbaker (Comment #357); Yamamoto (Comment #408); Palmer (Comment #484); Williams (Comment #494); Marler (Comment #504); Koop (Comment #506); Korth (Comment #516); Lai (Comment #541); Piersol (Comment #571). *See also* Senator Perdue (Comment #569).

[381] 1–800 CONTACTS (Comment #568); Warby Parker (Comment #593).

[382] *Id.*

[383] 5 U.S.C. 57a.

[384] The state optometric associations also encouraged the Commission to do more to ''ensure that patients are aware that contact lenses are regulated medical devices, whose safe use and optimal performance depends on eye examinations and professional supervision.'' Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

[385] Furthermore, the Commission believes that the proposed Rule amendment requiring a signed acknowledgment of receipt of a contact lens prescription will also aid Rule enforcement efforts. *See supra* Section III.A.3.

[386] *See* 15 U.S.C. 7608; 16 CFR 315.9.

[387] American Optometric Association (Comment #644); Virginia Optometric Association (Comment #16); Wisconsin Optometric Association (Comment #30); Utah Optometric Association (Comment #39); Pennsylvania Optometric Association (Comment #46); Alabama Optometric Association (Comment #48); Iowa Optometric Association (Comment #79); Michigan Optometric Association (Comment #86); California Optometric Association (Comment #119); New Mexico Optometric Association (Comment #211); Mississippi Optometric Association (Comment #548); Ohio Optometric Association (Comment #556); Connecticut Association of Optometrists (Comment #560); North Carolina State Optometric Society (Comment #567); Tennessee Association of Optometric Physicians (Comment #575); Colorado Optometric Association (Comment #584); New Jersey Society of Optometric Physicians (Comment #595).

[388] Comment #644.

[389] *Id.*

[390] Comment #621.

[391] *Id.*

[392] Comments ##536, 545.

to file complaints against their eye care provider, as well as replacement contact lens resellers. Likewise, some online retailers recommended that to facilitate enforcement efforts the Commission should ''create a user-friendly online complaint process for consumers.'' [393] These commenters argued that the online complaint assistant is difficult to navigate and does not ask the appropriate questions to identify a Rule violation.[394]

After careful consideration of these comments, the Commission declines to redesign its complaint reporting mechanism. The Commission has designed the FTC Complaint Assistant, the agency's online complaint reporting system, to be responsive to consumers who wish to file complaints about more than a hundred different types of products or services, while at the same time facilitating the filing of complaints regarding the most common complaint areas. Accordingly, the home page of the complaint system contains primary links for the FTC's seven most common complaint areas. The Commission's goal is that the primary links on the home page be responsive to at least 80 percent of the consumer complaints the agency receives. Although highlighting the most frequent types of complaints necessarily means that many areas of concern cannot be listed as separate categories, users can easily submit their complaint under the category ''Other'' when there is no listed category for the complaint, as is the case with contact lenses. Once the ''Other'' category is selected, the subsequent Web page includes the ''Health and Fitness'' subcategory, which is described as including, ''prescriptions, eye care.'' After screening out complaints related to telemarketing phone calls and spam email, the first option on the following Web page asks whether the complaint relates to ''Eyeglasses or Contact Lenses.'' During this process, the person lodging the complaint is given ample room to describe the details of the complaint.

Instructions on the FTC Complaint Assistant page explain that the FTC will categorize a complaint even if it does not fit one of the listed categories. In addition, the Web page also informs users that if they are ''having trouble categorizing [their] complaint,'' they can chat online with FTC tech support. Accordingly, the Commission believes that the FTC Complaint Assistant is configured to capture and report all contact lens-related complaints, whether they originate from consumers, prescribers, sellers, or others. However, resources permitting, the Commission will explore whether a dedicated email address would also be beneficial to complement the Complaint Assistant.

VI. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 30, 2017. Write ''Contact Lens Rule, 16 CFR part 315, Project No. R511995'' on the comment. Your comment, including your name and your state, will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comments to be withheld from the public record. Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/contactlensrule* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home.* you also may file a comment through that Web site.

If you file your comment on paper, write ''Contact Lens Rule, 16 CFR Part 315, Project No. R511995'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex C), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex C), Washington, DC 20024.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 30, 2017. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

The Commission invites members of the public to comment on any issues or concerns they believe are relevant or appropriate to the Commission's consideration of proposed amendments to the Rule. The Commission requests you provide factual data, and in particular, empirical data, upon which your comments are based. In addition to the issues raised above, the Commission solicits public comment on the costs and benefits to industry members and consumers of each of the proposals as well as the specific questions identified below. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

Questions

A. General Questions on Proposed Amendments: To maximize the benefits

[393] 1–800 CONTACTS (Comment #568); Warby Parker (Comment #593). *See also* LD Vision Group (Comment #544) (recommending that the Commission ''[c]reate an online reporting mechanism for sellers and consumers to report unfair prescriber practices'').

[394] 1–800 CONTACTS (Comment #568); Warby Parker (Comment #593).

and minimize the costs for prescribers and sellers (including small businesses), the Commission seeks views and data on the following general questions for each of the proposed changes described in this NPRM:

1. What benefits would a proposed change confer and on whom? The Commission in particular seeks information on any benefits a change would confer on consumers of contact lenses.

2. What costs or burdens would a proposed change impose and on whom? The Commission in particular seeks information on any burdens a change would impose on small businesses.

3. What regulatory alternatives to the proposed changes are available that would reduce the burdens of the proposed changes while providing the same benefits?

4. What additional information, tools, or guidance might the Commission provide to assist industry in meeting extant or proposed requirements efficiently?

5. What evidence supports your answers?

B. Acknowledgment of prescription release:

1. Would the proposed amendment to require prescribers, after the completion of a contact lens fitting, to request the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their contact lens prescription after the completion of the contact lens fitting? Why?

2. Would the proposed amendment to require prescribers to maintain copies of the signed acknowledgments for a period of not less than three years increase, decrease, or have no effect on the Commission's ability to measure and enforce the Rule's automatic prescription release provision? Why?

3. Would the proposed amendment to require the acknowledgment form to inform patients that they may purchase contact lenses from the seller of their choice increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

4. Should the Commission consider other language to be included in the signed acknowledgment form? If so, what?

5. Would allowing the acknowledgment form to be in either paper or electronic format increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? What other factors should the Commission consider to lower the cost and improve the reliability of executing, storing, and retrieving the signed acknowledgment forms?

6. Should the proposed amendment contain specific language about the use of electronic acknowledgment forms and electronic signatures? If so, what? Should the proposed amendment contain particular requirements about the type of electronic acknowledgment forms and electronic signatures to be used? If so, what types should be required?

7. Are there alternate ways to structure a patient acknowledgment requirement that would reduce the burdens of the proposed amendment while providing the same, or greater, benefits?

8. What evidence supports your answers?

C. Additional mechanisms for improving prescription portability:

1. The Commission believes that the use of patient portals to provide patients with access to electronic copies of their prescriptions would benefit prescribers, sellers, and patients. The Commission seeks comment on the benefits or burdens that the use of patient portals would confer.

2. The Commission seeks comment on the level of adoption of patient portals. Do prescribers use patient portals? Do patients use them? What are the rates of patient adoption when prescribers make them available?

3. What characteristics should patient portals have in order to best promote prescription portability?

4. Do patient portals have the potential to allow prescribers to comply with the automatic prescription release requirements of the Rule? If so, how? Do patient portals have limitations that would prevent them from being used by prescribers to comply with the automatic prescription release requirements of the Rule? If so, what are they?

5. If the Commission were to determine that patient portals could be used to comply with the automatic prescription release requirements of the Rule, how would this determination affect the requirement that prescribers obtain a signed acknowledgment form from patients? Do patient portals have characteristics that could serve as a substitute for the signed acknowledgment form?

6. What other technologies are available that could be implemented to improve prescription portability and thereby increase benefits and decrease burdens related to prescription release?

7. What evidence supports your answers?

D. Additional copies of prescriptions:

1. In this NPRM, the Commission has preliminarily determined that requiring prescribers to provide additional copies of contact lens prescriptions to a patient upon request is required by the Act. How does this determination affect, if at all, the portability of contact lens prescriptions?

2. Does this determination affect the accuracy of contact lens prescriptions presented to sellers? If so, how?

3. Does this determination affect the administrative burden of prescribers? If so, how? Would any burden caused by this determination be offset by a reduced burden related to prescription verification requests? If so, how?

4. What evidence supports your answers?

E. Sellers designated to act on behalf of patients:

1. Should the Commission impose a timeframe for prescribers, under Section 315.3(a)(2) of the Rule, to respond to requests from authorized third parties for a copy of a patient's prescription?

2. If so, what would be the appropriate amount of time for a prescriber to be required to respond to a request from an authorized third party for a copy of a patient's prescription?

3. What evidence supports your answers?

F. Presentation of prescription ''directly or by facsimile'' under Section 315.5(a)(1):

1. The Commission has initially determined that presenting a prescription to a seller ''directly or by facsimile'' includes the use of online patient portals. Does this determination further the Act's goal of prescription portability? If so, how?

2. What is the impact, including costs and benefits, of this determination?

3. What evidence supports your answers?

G. Automated telephone systems as ''direct communication'' under Section 315.5(a)(2):

1. What modifications to automated telephone calls, short of prohibiting the use of such calls, should the Commission consider to address the concerns raised by prescribers about the burden of such calls?

H. Section 315.5(e)—No alteration of prescription provision:

1. To conform the language of the Rule to the language of the Act, the Commission proposes to amend Section 315.5(e) to strike the words ''private label.'' Would this proposed amendment alter the way that prescribers, sellers, or manufacturers do business, and if so, how?

2. Are there alternative proposals that the Commission should consider?

3. What evidence supports your answers?

VII. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. See 16 CFR 1.26(b)(5).

VIII. Paperwork Reduction Act

The existing Rule contains recordkeeping and disclosure requirements that constitute ''information collection requirements'' as defined by 5 CFR 1320.3(c) under Office of Management and Budget (''OMB'') regulations that implement the Paperwork Reduction Act (''PRA''), 44 U.S.C. 3501 *et seq.* OMB has approved the Rule's existing information collection requirements. (OMB Control No. 3084–0127).

The proposed modifications to the Rule would require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed acknowledgment form, entitled ''Patient Receipt of Contact Lens Prescription,'' confirming that patients received their contact lens prescriptions at the completion of their contact lens fitting. The proposed recordkeeping requirement would constitute an information collection as defined by 5 CFR 1320.3(c). Accordingly, the Commission is providing PRA burden estimates for them, as set forth below. The Commission will also submit this notice of proposed rulemaking and associated Supporting Statement to OMB for review under the PRA. The proposed requirement that prescribers provide an acknowledgment form to patients, however, does not constitute an information collection under the PRA, in that the Rule specifies the language that the form must contain.[395]

A. Estimated Additional Hours Burden

Commission staff estimates the paperwork burden of the proposed modifications based on its knowledge of the eye care industry. The staff believes there will be an additional burden on individual prescribers' offices to maintain the signed acknowledgment forms for a period of not less than three years.

The number of contact lens wearers in the United States is currently estimated to be approximately 41 million.[396] Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 41 million people would read and sign an acknowledgment form every year.[397]

Maintaining the form for a period of not less than three years does not impose a substantial new burden on individual prescribers and their office staff. The majority of states already require that optometrists maintain records of eye examinations for at least three years,[398] and maintaining a one-page acknowledgment form per patient per year should not take more than a few seconds of time, and an inconsequential, or *de minimis,* amount of record space. Some prescribers might present the acknowledgment form electronically, and such format would allow the signed acknowledgment to be preserved without any additional burden. For other prescribers, the new recordkeeping requirement would likely require that office staff either preserve the signed acknowledgment form in paper format or electronically scan the signed acknowledgment form and save it as an electronic document. In the latter scenario, the Commission estimates this scanning and saving would take approximately one minute. The Commission does not possess any information regarding the percentage of prescribers' offices that use paper forms, electronic forms, or that scan paper files and maintain them electronically. Therefore, for purposes of this notice, staff will assume that *all* prescriber offices require a full one minute per form per year for record maintenance purposes arising from the proposed modifications.

As noted above, the number of contact lens wearers in the United States is currently estimated to be approximately 41 million. Therefore, assuming one signed acknowledgment form for each contact lens wearer per year, prescribers' offices, collectively, would have to spend approximately 41 million minutes, or 683,333 hours, per year maintaining records of eye examinations (recordkeeping requirement).

In all likelihood, the actual overall increased burden on prescribers may be less than 683,333 hours, because increasing the number of patients in possession of their prescriptions should correspondingly increase the number of consumers who provide their prescriptions to third-party sellers when purchasing contact lenses. This, in turn, should reduce the number of verification requests that third-party sellers would otherwise make to prescribers. Based on current estimates, responding to verification requests requires that prescribers spend approximately five minutes per request.[399] The Commission, however, does not presently have enough information to devise a reliable estimate for how many more consumers are likely to present third-party sellers with a complete copy of their prescription following the proposed Rule modification. Therefore, for purposes of calculating the burden, the Commission, at this time, will not credit the expected reduction in verification burden.

B. Estimated Total Labor Cost Burden

Commission staff derives labor costs by applying appropriate hourly cost figures to the burden hours described above. The Commission assumes that office clerks will perform most of the labor when it comes to printing, disseminating, and storing the acknowledgment forms for prescribers' offices. According to Bureau of Labor Statistics, general office clerks earn an average wage of $15.33 per hour.[400] Based on this data, the estimated total additional labor cost attributable to the proposed modifications to the Rule would amount to approximately $10,475,495.

While not insubstantial, this amount constitutes just under one-fourth of one percent of the estimated overall retail market for contact lens sales in the

[395] The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a ''collection of information.'' 5 CFR 1320.3(c)(2).

[396] Cope, *supra* note 29, at 866.

[397] In the past, some commenters have suggested that typical contact lens wearers obtain annual exams every 18 months or so, rather than one every year. However, because most prescriptions are valid for a minimum of one year under the Rule, and use of a longer exam cycle would lead to an estimate of a lower number of signed acknowledgment forms and a reduced burden, we continue to estimate that patients seek exams every 12 months.

[398] *See, e.g.,* 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246–851–290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645–182.2(2) (requiring optometrists to maintain patient records for at least five years); Fla. Admin. Code r. 64B13–3.003(6) (requiring optometrists to maintain patient records for at least five years).

[399] *See* American Optometric Association, Comment in response to the Agency Information Collection Activities; Proposed Collection; Comment Request, 81 FR 31938 (May 20, 2016), *https://www.ftc.gov/policy/public-comments/initiative-665.*

[400] Press Release, U.S. Dep't of Labor, Bureau of Labor Statistics, ''Occupational Employment Statistics—May 2015,'' *http://www.bls.gov/news.release/ocwage.t01.htm.*

United States.[401] Furthermore, the burden is likely to be less, because many prescribers' offices will not require a full minute to store the acknowledgment form. And, as noted above, increasing the number of patients in possession of their prescriptions should correspondingly increase the number of consumers who provide their prescriptions to third-party sellers when purchasing contact lenses. This, in turn, could potentially reduce the number of verification requests made to prescribers, and the time prescribers spend responding.

The Commission invites comments on: (1) 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; (2) the accuracy of the FTC's burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collecting information.

Comments on the information collection requirements subject to review under the PRA should also be submitted to Office of Management and Budget. If sent by U.S. mail, address comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395–5167.

IX. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'')[402] requires the Commission to conduct an analysis of the anticipated economic impact of the proposed amendments on small entities.[403] The purpose of a regulatory flexibility analysis is to ensure the agency considers the impacts on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA[404] provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.

The Commission does not anticipate that the proposed amendments will have a significant economic impact on small entities, although they may affect a substantial number of small businesses. The proposed amendments require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed acknowledgment form, entitled ''Patient Receipt of Contact Lens Prescription,'' confirming that patients received their contact lens prescriptions at the completion of their contact lens fitting. The Commission believes the burden of complying with this requirement likely will be relatively small. As discussed in the Paperwork Reduction Act section, the majority of states already require that optometrists maintain records of eye examinations for at least three years. The proposed amendment would require one additional page to be maintained as a record, which is likely a minimal burden. Therefore, based on available information, the Commission certifies that amending the Rule as proposed will not have a significant economic impact on a substantial number of small businesses.

Although the Commission certifies under the RFA that the proposed amendment will not, if promulgated, have a significant impact on a substantial number of small entities, the Commission has nonetheless determined it is appropriate to publish an Initial Regulatory Flexibility Analysis to inquire into the impact of the proposed amendment on small entities. Therefore, the Commission has prepared the following analysis:

A. Description of the Reasons the Agency Is Taking Action

In response to public comments, the Commission proposes amending the Rule to ensure that patients are receiving a copy of their contact lens prescription at the completion of a contact lens fitting.

B. Statement of the Objectives of, and Legal Basis for, the Proposed Amendments

The objective of the proposed amendment is to clarify and update the Rule in accordance with marketplace practices. The legal basis for the Rule is the Fairness to Contact Lens Consumers Act.[405] The Act authorizes the Commission to implement its requirements through the issuance of rules.

C. Small Entities to Which the Proposed Amendments Will Apply

The proposed amendments apply to prescribers of contact lenses. The Commission believes that many prescribers will fall into the category of small entities (*e.g.,* offices of optometrists less than $7.5 million in size).[406] Determining a precise estimate of the number of small entities covered by the Rule's prescription release requirements is not readily feasible because most prescribers' offices do not release the underlying revenue information necessary to make this determination.[407] Based on its knowledge of the eye care industry, staff believes that a substantial number of these entities likely qualify as small businesses. The Commission seeks comment with regard to the estimated number or nature of small business entities, if any, for which the proposed amendments would have a significant impact.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply

As explained earlier in this document, the proposed amendments require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed acknowledgment form, entitled ''Patient Receipt of Contact Lens Prescription,'' confirming that patients received their contact lens prescriptions at the completion of their contact lens fitting.

The small entities potentially covered by these proposed amendments will include all such entities subject to the Rule. The professional skills necessary for compliance with the Rule as modified by the proposed amendments will include office and administrative support supervisors to create the acknowledgment form and clerical personnel to collect signatures from patients and maintain records. The Commission believes the burden imposed on small businesses by these requirements is relatively small, for the reasons described previously in Section

[401] According to The Vision Council, the contact lens sales market in the United States in 2015 totaled $4,664,200,000 at the retail level. *See* The Vision Council, ''U.S. Optical Industry Report Card,'' Dec. 2015. The estimated additional burden of $10,475,495 thus amounts to approximately 0.22% of the total market.

[402] 5 U.S.C. 601–612.

[403] The Commission also conducted an RFA analysis of prior amendments to the Rule implementing the Fairness to Contact Lens Consumers Act. 69 FR 40482, 40507 (July 2, 2004).

[404] 5 U.S.C. 605.

[405] 15 U.S.C. 7601–7610.

[406] *See* U.S. Small Business Admin., ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes,'' (eff. Feb. 26, 2016), *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

[407] 5 U.S.C. 601(6).

VIII of this notice. The Commission invites comment and information on these issues, including estimates or data on specific compliance costs that small entities might be expected to incur.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other federal statutes, rules, or policies duplicating, overlapping, or conflicting with the proposed amendments, but as noted previously, the majority of states already require that optometrists—of which many are most likely small businesses—maintain records of eye examinations for at least three years. The Commission invites additional comment on this issue.

F. Significant Alternatives to the Proposed Amendments

The Commission has not proposed any specific small entity exemption or other significant alternatives, as the proposed amendments clarify and update the Rule in light of marketplace practices to ensure that patients are receiving a copy of their contact lens prescription at the completion of a contact lens fitting. Under these limited circumstances, the Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendments. As discussed above, the proposed recordkeeping requirement likely involves minimal burden and prescribers would be permitted to maintain records in either paper or electronic format. This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and input automatically into the electronic record. Furthermore, prescribers also could scan signed paper copies of the acknowledgment form and store those forms electronically to lower the costs of this recordkeeping requirement. Nonetheless, the Commission seeks comment on the need, if any, for alternative compliance methods to reduce the economic impact of the Rule on small entities. If the comments filed in response to this NPRM identify small entities affected by the proposed amendments, as well as alternative methods of compliance that would reduce the economic impact of the proposed amendments on such entities, the Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final Rule.

X. Proposed Rule Language

List of Subjects in 16 CFR Part 315

Advertising, Medical devices, Ophthalmic goods and services, Trade practices.

Under 15 U.S.C 7601–7610 and as discussed in the preamble, the Federal Trade Commission proposes to amend title 16 of the Code of Federal Regulations by revising part 315 as follows:

PART 315—CONTACT LENS RULE

■ 1. The authority citation for part 315 continues to read as follows:

Authority: Pub. L. 108–164, secs. 1–12; 117 Stat. 2024 (15 U.S.C. 7601–7610).

■ 2. Amend § 315.3 by adding paragraph (c) to read as follows:

§ 315.3 Availability of contact lens prescriptions to patients.

* * * * *

(c) *Acknowledgment of prescription release.* Upon completion of a contact lens fitting, and after providing a copy of the contact lens prescription to the patient, the prescriber:

(1) Shall request that the contact lens patient acknowledge receipt of the contact lens prescription by signing an acknowledgment form entitled, ''Patient Receipt of Contact Lens Prescription'' that states, ''My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand I am free to purchase contact lenses from the seller of my choice.''

(2) The acknowledgment form shall include, in addition to the title and statement specified in paragraph (c)(1), the name of the patient, the patient signature, and the date executed. In the event that the patient declines to sign the acknowledgment form, the prescriber shall note the patient's refusal on the form and sign it. No other statements or information, other than the address or letterhead of the prescriber, shall be placed on the acknowledgment form.

(3) The prescriber shall maintain the signed acknowledgments received under paragraph (c)(1) for a period of not less than three (3) years, and such signed acknowledgments shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

■ 3. Amend § 315.5 paragraph (e) by revising the second sentence to read as follows:

§ 315.5 Prescriber verification.

* * * * *

(e) * * * Notwithstanding the preceding sentence, a seller may substitute for contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–28471 Filed 12–6–16; 8:45 am]

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Part VI

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Covered Asset Acquisitions; Proposed Rule

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

[REG 129128–14]

RIN 1545–BM36

Covered Asset Acquisitions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference in part to temporary regulations.

SUMMARY: This document contains proposed Income Tax Regulations under section 901(m) of the Internal Revenue Code (Code) with respect to transactions that generally are treated as asset acquisitions for U.S. income tax purposes and either are treated as stock acquisitions or are disregarded for foreign income tax purposes. In the Rules and Regulations section of this issue of the **Federal Register**, temporary regulations are being issued under section 901(m) (the temporary regulations), the text of which serves as the text of a portion of these proposed regulations. These regulations are necessary to provide guidance on applying section 901(m). These regulations affect taxpayers claiming foreign tax credits.

DATES: Comments and requests for a public hearing must be received by March 7, 2017.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–129128–14), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–129128–14), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20044, or sent electronically, via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–129128–14).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Jeffrey L. Parry, (202) 317–6936; concerning submissions of comments, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Section 901(m)

Section 212 of the Education Jobs and Medicaid Assistance Act (EJMAA), enacted on August 10, 2010 (Pub. L. 111–226), added section 901(m) to the Code. Section 901(m)(1) provides that, in the case of a covered asset acquisition (CAA), the disqualified portion of any foreign income tax determined with respect to the income or gain attributable to relevant foreign assets (RFAs) will not be taken into account in determining the foreign tax credit allowed under section 901(a), and, in the case of foreign income tax paid by a section 902 corporation (as defined in section 909(d)(5)), will not be taken into account for purposes of section 902 or 960. Instead, the disqualified portion of any foreign income tax (the disqualified tax amount) is permitted as a deduction. See section 901(m)(6).

Under section 901(m)(2), a CAA is (i) a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies; (ii) any transaction that is treated as an acquisition of assets for U.S. income tax purposes and as the acquisition of stock of a corporation (or is disregarded) for purposes of a foreign income tax; (iii) any acquisition of an interest in a partnership that has an election in effect under section 754; and (iv) to the extent provided by the Secretary, any other similar transaction. The Joint Committee on Taxation's technical explanation of EJMAA states that it is anticipated that the Secretary will issue regulations identifying other similar transactions that result in an increase to the basis of assets for U.S. income tax purposes without a corresponding increase for foreign income tax purposes. Staff of the Joint Committee on Taxation, Technical Explanation of the Revenue Provisions of the Senate Amendment to the House Amendment to the Senate Amendment to H.R. 1586, Scheduled for Consideration by the House of Representatives on August 10, 2010, at 14 (Aug. 10, 2010) (JCT Explanation).

Section 901(m)(3)(A) provides that the term ''disqualified portion'' means, with respect to any CAA, for any taxable year, the ratio (expressed as a percentage) of (i) the aggregate basis differences (but not below zero) allocable to such taxable year with respect to all RFAs; divided by (ii) the income on which the foreign income tax referenced in section 901(m)(1) is determined. If the taxpayer fails to substantiate the income on which the foreign income tax is determined to the satisfaction of the Secretary, such income will be determined by dividing the amount of such foreign income tax by the highest marginal tax rate applicable to the taxpayer's income in the relevant jurisdiction. The JCT Explanation states that for this purpose the income on which the foreign income tax is determined is the income as determined under the law of the relevant jurisdiction. See JCT Explanation at 14.

Section 901(m)(3)(B)(i) provides the general rule that the basis difference with respect to any RFA will be allocated to taxable years using the applicable cost recovery method for U.S. income tax purposes. Section 901(m)(3)(B)(ii) provides that, except as otherwise provided by the Secretary, if there is a disposition of an RFA, the basis difference allocated to the taxable year of the disposition will be the excess of the basis difference of such asset over the aggregate basis difference of such asset that has been allocated to all prior taxable years. The statute further provides that no basis difference with respect to such asset will be allocated to any taxable year thereafter.

Section 901(m)(3)(C)(i) provides that basis difference means, with respect to any RFA, the excess of: (i) The adjusted basis of such asset immediately after the CAA, over (ii) the adjusted basis of such asset immediately before the CAA. If the adjusted basis of an RFA immediately before the CAA exceeds the adjusted basis of the RFA immediately after the CAA (that is, where the adjusted basis of an asset with a built-in loss is reduced in a CAA), such excess is taken into account as a basis difference of a negative amount. See section 901(m)(3)(C)(ii).

The JCT Explanation states that, for purposes of determining basis difference, it is the tax basis for U.S. income tax purposes that is relevant and not the tax basis as determined under the law of the relevant jurisdiction. See JCT Explanation at 14. However, the JCT Explanation further states that it is anticipated that the Secretary will issue regulations identifying those circumstances in which, for purposes of determining the adjusted basis of such assets immediately before the CAA, it may be acceptable to use foreign basis or another reasonable method. Id.

Section 901(m)(4) provides that an RFA means, with respect to a CAA, any asset (including goodwill, going concern value, or other intangible) with respect to such acquisition if income, deduction, gain, or loss attributable to such asset is taken into account in determining the foreign income tax referenced in section 901(m)(1).

Section 901(m)(7) provides that the Secretary may issue regulations or other guidance as is necessary or appropriate to carry out the purposes of section 901(m), including to exempt from its application certain CAAs and RFAs with respect to which the basis difference is de minimis. The JCT

Explanation states that regulations may also exclude from the application of section 901(m) CAAs that are not taxable for U.S. income tax purposes, or in which the basis of the RFAs is also increased for purposes of the law of the relevant foreign jurisdiction. See JCT Explanation at 16.

Section 901(m) generally applies to CAAs occurring after December 31, 2010. Section 901(m), however, does not apply to any CAA with respect to which the transferor and transferee are not related if the acquisition is made pursuant to a written agreement that was binding on January 1, 2011, and at all times thereafter; described in a ruling request submitted to the IRS on or before July 29, 2010; or described on or before January 1, 2011, in a public announcement or in a filing with the Securities and Exchange Commission. See EJMAA, section 212(b).

II. Notices 2014–44 and 2014–45

The Department of the Treasury (Treasury Department) and the IRS issued Notice 2014–44 (2014–32 I.R.B. 270 (July 21, 2014)) and Notice 2014–45 (2014–34 I.R.B. 388 (July 29, 2014)), announcing the intent to issue regulations addressing the application of section 901(m) to dispositions of RFAs following CAAs and to CAAs described in section 901(m)(2)(C) (regarding section 754 elections). In addition, the notices announced the intent to issue regulations providing successor rules for the continued application of section 901(m) after subsequent transfers of RFAs with remaining basis difference. The temporary regulations issued in the Rules and Regulations section of this issue of the **Federal Register** provide the rules described in those Notices.

Explanation of Provisions

I. Overview

These proposed regulations provide rules for computing the disqualified portion of foreign income taxes under section 901(m). Proposed § 1.901(m)–1 provides definitions that apply for purposes of the proposed regulations. Proposed § 1.901(m)–2 identifies the transactions that are CAAs, including additional categories of transactions that are identified as CAAs pursuant to the authority granted in section 901(m)(2)(D), and provides rules for identifying assets that are RFAs with respect to a CAA. Proposed § 1.901(m)–3 provides rules for computing the disqualified portion of foreign income taxes, describes the treatment under section 901(m)(1) of the disqualified portion, and provides rules for determining whether and to what extent basis difference that is assigned to a given taxable year is carried over to subsequent taxable years. Proposed § 1.901(m)–4 provides rules for determining the basis difference with respect to an RFA, including an election to use foreign basis for purposes of this determination. Proposed § 1.901(m)–5 provides rules for taking into account basis difference under an applicable cost recovery method or as a result of a disposition of an RFA, rules for allocating that basis difference, when necessary, to one or more persons subject to section 901(m), and rules for assigning that basis difference to a U.S. taxable year. Proposed § 1.901(m)–6 provides successor rules for applying section 901(m) to subsequent transfers of RFAs that have basis difference that has not yet been fully taken into account, as well as for transferring an aggregate basis difference carryover of a person subject to section 901(m) either to another aggregate basis difference carryover account of such person or to another person subject to section 901(m). Proposed § 1.901(m)–7 provides de minimis rules under which certain basis differences are not taken into account under section 901(m). Proposed § 1.901(m)–8 provides guidance on the application of section 901(m) to pre-1987 foreign income taxes and anti-abuse rules relating to built-in loss assets.

II. Relevance of the Terms Section 901(m) Payor, Foreign Payor, RFA Owner (U.S.), and RFA Owner (Foreign)

As provided under proposed § 1.901(m)–1, a section 901(m) payor is a person that is eligible to claim the foreign tax credit allowed under section 901(a), regardless of whether the person chooses to claim the foreign tax credit, as well as a section 902 corporation. Therefore, a section 901(m) payor is the person required to compute a disqualified tax amount when section 901(m) applies. The foreign payor is the individual or entity (including a disregarded entity) subject to a foreign income tax. The RFA owner (U.S.) is the person that owns one or more RFAs for U.S. income tax purposes and therefore is required to report, or otherwise track, items of income, deduction, gain, or loss attributable to the RFAs for purposes of computing the U.S. taxable income of the RFA owner (U.S.). Similarly, the RFA owner (foreign) is the individual or entity (including a disregarded entity) that owns one or more RFAs for purposes of a foreign income tax and that therefore generally would report, or otherwise track, items of income, deduction, gain, or loss attributable to the RFAs for purposes of determining income reported on a foreign income tax return.

The section 901(m) payor may also be the foreign payor, the RFA owner (U.S.), or the RFA owner (foreign), or any combination thereof; alternatively, the section 901(m) payor may not be any of them depending upon the application of the entity classification rules for U.S. income tax purposes. Further, the foreign payor and the RFA owner (foreign) may or may not be the same person for purposes of a foreign income tax depending upon whether the RFA owner (foreign) is a fiscally transparent entity for purposes of the foreign income tax. For example, if a foreign corporation, which is a section 902 corporation, owns RFAs and is the entity that is subject to a foreign income tax under the relevant foreign law, the foreign corporation is the section 901(m) payor, foreign payor, RFA owner (U.S.), and RFA owner (foreign). As another example, if two U.S. corporations each own a 50 percent interest in a partnership and the partnership owns a disregarded entity that is subject to a foreign income tax and that, for purposes of the foreign income tax, owns one or more RFAs, the corporate partners are each a section 901(m) payor, the disregarded entity is the foreign payor and the RFA owner (foreign), and the partnership is the RFA owner (U.S.).

Finally, because the computation of a section 901(m) payor's disqualified tax amount is based on items determined at the level of the foreign payor, the RFA owner (U.S.), and the RFA owner (foreign), the regulations provide rules for allocating those items when the section 901(m) payor is not the foreign payor, the RFA owner (U.S.), or the RFA owner (foreign), or any combination thereof.

III. CAAs and RFAs

A. CAAs

Proposed § 1.901(m)–2(b) identifies six categories of transactions that constitute CAAs, three of which are specified in the statute (incorporated by cross reference to the temporary regulations) and three of which are additional categories of transactions that are identified as CAAs pursuant to the authority granted under section 901(m)(2)(D). In addition, for transactions that occurred on or after January 1, 2011, and before the general applicability date of the temporary regulations (referred to as the ''transition period'' in the preamble to the temporary regulations and in this

preamble), proposed § 1.901(m)–2(d) (incorporated by cross reference to the temporary regulations) defines CAAs by reference to the statutory definition under section 901(m)(2). Transactions are CAAs regardless of whether any gain, income, loss, or deduction realized in connection with the transaction is taken into account for U.S. income tax purposes. However, basis difference resulting from a CAA may not be taken into account under section 901(m) pursuant to de minimis rules in proposed § 1.901(m)–7.

Proposed § 1.901(m)–2(b)(1) through (4) describes four specific types of transactions that are generally expected to result in an increase in the basis of assets for U.S. income tax purposes without a corresponding increase in basis for foreign income tax purposes. This is because these transactions generally are treated as an acquisition of assets for U.S. income tax purposes and either are treated as an acquisition of stock or of a partnership interest or are disregarded for foreign income tax purposes. The other two categories of transactions described in proposed § 1.901(m)–2(b)(5) and (6), which involve an acquisition of assets for both U.S. and foreign income tax purposes, are CAAs only if the transaction results in an increase in the basis of an asset for U.S. income tax purposes but not for foreign income tax purposes. Such transactions may include, for example, an acquisition of assets that is structured to avoid the application of the Code's corporate nonrecognition provisions, such as section 332, 351, or 361, while still qualifying for nonrecognition treatment for foreign income tax purposes.

B. RFAs

Proposed § 1.901(m)–2(c)(1) incorporates by cross reference to the temporary regulations the general definition of an RFA, which provides that an RFA means, with respect to a foreign income tax and a CAA, any asset (including goodwill, going concern value, or other intangible) subject to the CAA that is relevant in determining foreign income for purposes of the foreign income tax. In addition, for CAAs that occurred during the transition period, proposed § 1.901(m)–2(d) (incorporated by cross reference to the temporary regulations) defines RFAs by reference to the statutory definition under section 901(m)(4).

Proposed § 1.901(m)–2(c)(2) generally provides that an asset is relevant in determining foreign income if income, deduction, gain, or loss attributable to such asset is or would be taken into account in determining foreign income immediately after the CAA. Proposed § 1.901(m)–2(c)(3) provides, however, that, after a CAA, an asset will become an RFA with respect to another foreign income tax if, pursuant to a plan or series of related transactions that have a principal purpose of avoiding the application of section 901(m), an asset that is not relevant in determining foreign income for purposes of that foreign income tax immediately after the CAA later becomes relevant in determining such foreign income. A principal purpose of avoiding section 901(m) will be deemed to exist if income, deduction, gain, or loss attributable to the asset is taken into account in determining such foreign income within the one-year period following the CAA.

IV. Disqualified Tax Amount and Aggregate Basis Difference Carryover

A. Disqualified Tax Amount

Proposed § 1.901(m)–3 sets forth the rules for computing the disqualified portion of foreign income taxes (referred to in the regulations as the ''disqualified tax amount''). Proposed § 1.901(m)–3 also sets forth the treatment under section 901(m)(1) of the disqualified tax amount and provides rules for determining whether and to what extent basis difference that is assigned to a given U.S. taxable year is carried over to subsequent U.S. taxable years (referred to in the regulations as ''aggregate basis difference carryover'').

In general, a disqualified tax amount is computed separately for each foreign tax return that takes into account income, gain, deduction, or loss from one or more RFAs in computing the foreign taxable income and for each section 901(m) payor that pays or accrues, or that is considered to pay or accrue, a portion of the foreign income taxes reflected on the foreign tax return. Furthermore, if the foreign income taxes relate to more than one separate category described in § 1.904–4(m) (including section 904(d) categories), a separate disqualified tax amount computation is done for each such separate category. Members of a U.S. affiliated group of corporations (as defined in section 1504) that file a consolidated return are each treated as a separate section 901(m) payor; therefore, disqualified tax amounts are computed at the member-level.

The proposed regulations refer to the total taxable income (or loss) that is computed under foreign law for a foreign taxable year and reflected on a foreign tax return as ''foreign income'' and the total amount of tax reflected on a foreign tax return as a ''foreign income tax amount.'' Thus, foreign income does not include income that is exempt from the foreign income tax. The proposed regulations use the term ''foreign country creditable taxes'' (or ''FCCTs'') to refer to any foreign income taxes imposed by another foreign country or possession of the United States that were allowed under the relevant foreign law as a credit to reduce the foreign income tax amount and for which a credit is allowed under section 901 or 903. In addition, the proposed regulations define ''foreign income tax '' (by cross reference to the temporary regulations) to mean any income, war profits, or excess profits tax for which a credit is allowable under section 901 or 903, other than any withholding tax determined on a gross basis as described in section 901(k)(1)(B).

The foreign income, foreign income tax amount, and any FCCTs are determined at the foreign-payor level. If the foreign payor is not a section 901(m) payor, current law provides rules for determining the person that is considered to pay or accrue a foreign income tax amount for purposes of the foreign tax credit (see, for example, §§ 1.702–1(a)(6) and 1.901–2(f)). Those rules are not changed by these proposed regulations and therefore apply for purposes of determining the extent to which a foreign income tax amount is paid or accrued by, or considered paid or accrued by, a section 901(m) payor for purposes of section 901(m).

Proposed § 1.901(m)–3(b) sets forth the treatment of the disqualified tax amount and the computation of the disqualified tax amount. Pursuant to section 901(m)(1) and proposed § 1.901(m)–3(b)(1), the disqualified tax amount is not taken into account for purposes of determining foreign tax credits under section 901, 902, or 960. A section 901(m) payor must compute a disqualified tax amount for any U.S. taxable year for which it is assigned a portion of the basis difference with respect to one or more RFAs.

The disqualified tax amount is the lesser of the tentative disqualified tax amount and the foreign income tax amount paid or accrued by, or considered paid or accrued by, a section 901(m) payor. The tentative disqualified tax amount is determined using a modified version of the formula provided in section 901(m)(3). To determine the tentative disqualified tax amount, the foreign income tax amount paid or accrued by, or considered paid or accrued by, the section 901(m) payor for its U.S. taxable year (multiplicand) is multiplied by a ratio (disqualified ratio), the numerator of which is the sum of the portion of the basis

difference for all RFAs that is taken into account and assigned to the U.S. taxable year of the section 901(m) payor, and the denominator of which is the portion of the foreign income reflected on the foreign tax return that relates to the foreign income tax amount included in the multiplicand. The numerator and the denominator of the disqualified ratio are referred to in the proposed regulations as the ''aggregate basis difference'' and ''allocable foreign income,'' respectively.

Allocable foreign income (the denominator of the disqualified ratio) and the foreign income tax amount (the multiplicand) are determined using the total amount of foreign income and foreign income tax amount reflected on the foreign income tax return that are allocable to the section 901(m) payor, instead of by reference only to the amounts determined with respect to the RFAs. The Treasury Department and the IRS have determined that this approach appropriately carries out the purposes of section 901(m) while avoiding the administrative and compliance burdens that would result from a requirement to trace amounts of income to RFAs and identify the portion of foreign income taxes imposed on that income.

If a foreign income tax amount is computed taking into account an FCCT, the multiplicand of the tentative disqualified tax amount computation is the sum of the foreign income tax amount and any FCCTs paid or accrued by, or considered paid or accrued by, the section 901(m) payor. The Treasury Department and the IRS have determined that it is appropriate to include any FCCTs in the multiplicand to better reflect the effective tax rate imposed on the aggregate basis difference. However, the tentative disqualified tax amount is reduced (but not below zero) to the extent any portion of the FCCTs is itself treated as a disqualified tax amount of the section 901(m) payor with respect to a different foreign income tax.

The aggregate basis difference in the numerator includes cost recovery amounts and disposition amounts taken into account with respect to RFAs and assigned to the U.S. taxable year of the section 901(m) payor under proposed § 1.901(m)–5, as discussed in section VI. of this the Explanation of Provisions of this preamble. When the numerator and denominator are both positive amounts, the amount of aggregate basis difference included in the numerator is limited to the amount of foreign income in the denominator of the disqualified ratio (in other words, the allocable foreign income). This limitation ensures that multiplying the foreign income tax amount included in the multiplicand by the disqualified ratio would not produce a disqualified tax amount greater than 100 percent of the foreign income tax amount. See section IV.B. of the Explanation of Provisions section of this preamble for the treatment of any excess of the aggregate basis difference over the allocable foreign income as an aggregate basis difference carryover.

The denominator of the disqualified ratio is the allocable foreign income. When the entire foreign income tax amount reflected on a foreign tax return is paid or accrued by, or considered paid or accrued by, a single section 901(m) payor for U.S. income tax purposes, the allocable foreign income is simply the total foreign income reflected on the foreign tax return. In general, this will be the case when the section 901(m) payor is the foreign payor or owns a disregarded entity that is the foreign payor, unless there is a change in ownership or a change in entity classification in the foreign payor requiring an allocation of the foreign income tax amount of the foreign payor (a mid-year transaction).

If, however, the foreign income tax amount reflected on a foreign tax return is allocated to more than one person for U.S. income tax purposes, the allocable foreign income in the denominator of the disqualified ratio for a particular section 901(m) payor is equal to the portion of the foreign income reflected on the foreign tax return that relates to the foreign income tax amount allocated to, and considered paid or accrued by, that section 901(m) payor (and therefore that is included in the multiplicand of the tentative disqualified tax amount computation). Proposed § 1.901(m)–3(b)(2)(iii)(C) provides guidance on how to determine the allocable foreign income in three types of cases: (i) The foreign income tax amount is allocated to a section 901(m) payor because the foreign payor is involved in a mid-year transaction, such as the transfer of a disregarded entity during the disregarded entity's foreign taxable year or acquisitions involving elections under section 338 or 336(e); (ii) the foreign income tax amount is allocated to a section 901(m) payor that is a partner because the foreign payor is a partnership for U.S. income tax purposes that is legally liable for the foreign income tax amount under § 1.901–2(f)(4)(i) (or the foreign payor is a disregarded entity and its assets are owned for U.S. income tax purposes by an entity that is treated as a partnership for U.S. income tax purposes and that is legally liable for the foreign income tax amount under § 1.901–2(f)(4)(ii)); and (iii) the foreign income tax amount is allocated to a section 901(m) payor under § 1.901–2(f)(3)(i) because the section 901(m) payor is a member of a group whose income is taxed on a combined basis for foreign income tax purposes.

Notwithstanding the rules described in the two preceding paragraphs for determining allocable foreign income, if a section 901(m) payor fails to substantiate its allocable foreign income to the satisfaction of the Secretary, then proposed § 1.901(m)–3(b)(2)(iii)(D) provides that allocable foreign income will equal the amount determined by dividing the sum of the foreign income tax amount and the FCCTs that are paid or accrued by, or considered paid or accrued by, the section 901(m) payor, by the highest marginal tax rate applicable to income of the foreign payor under the relevant foreign income tax. See section 901(m)(3)(A).

If the numerator is less than zero, the denominator is less than or equal to zero, or the multiplicand is zero, the tentative disqualified tax amount (and therefore the disqualified tax amount) is zero. If the disqualified tax amount for a year either is zero or is limited by the foreign income tax amount paid or accrued by, or considered paid or accrued by, a section 901(m) payor, there will be an aggregate basis difference carryover as described in the next section.

B. Aggregate Basis Difference Carryover

Proposed § 1.901(m)–3(c) provides rules for determining the amount of aggregate basis difference carryover for a given U.S. taxable year of a section 901(m) payor that will be included in the section 901(m) payor's aggregate basis difference for the next U.S. taxable year (and therefore included in the numerator of the disqualified ratio for purposes of the next year's disqualified tax amount computation). The carryover reflects the extent to which the aggregate basis difference for a U.S. taxable year has not yet given rise to a disqualified tax amount.

If the disqualified tax amount is zero, none of the aggregate basis difference gives rise to a disqualified tax amount and therefore the full amount of the section 901(m) payor's aggregate basis difference for that year will be reflected in an aggregate basis difference carryover (positive or negative).

If the disqualified tax amount is not zero, an aggregate basis difference carryover may still arise in two situations. First, if the aggregate basis difference exceeds the section 901(m) payor's allocable foreign income (the denominator of the disqualified ratio) and therefore the amount of the

aggregate basis difference included in the numerator is limited, the excess is reflected in an aggregate basis difference carryover. Second, if the tentative disqualified tax amount (which takes into account FCCTs) exceeds the foreign income tax amount paid or accrued by the section 901(m) payor (which does not include FCCTs), that excess tax amount is converted into an equivalent amount of aggregate basis difference that is reflected in an aggregate basis difference carryover. See Prop. § 1.901(m)–3(c)(2)(ii)(B).

V. Determination of Basis Difference

Proposed § 1.901(m)–4 incorporates by cross reference the general rules in the temporary regulations for determining basis difference. Under these rules, basis difference is determined separately with respect to each foreign income tax for which an asset is an RFA.

Proposed § 1.901(m)–4(c)(1) provides for a foreign basis election, pursuant to which basis difference is equal to the U.S. basis in the RFA immediately after the CAA less the foreign basis in the RFA immediately after the CAA (including any adjustments to the foreign basis resulting from the CAA). Proposed § 1.901(m)–4(c)(2) through (4) provide rules for making a foreign basis election. A foreign basis election generally is made by the RFA owner (U.S.). For example, in a section 338 CAA, the foreign basis election is made by the corporation that is the subject of the qualified stock purchase (new target as defined in § 1.338–2(c)(17)). If the RFA owner (U.S.) is a partnership, however, each partner in the partnership (and not the partnership) may independently make a foreign basis election. A foreign basis election is made separately for each CAA and with respect to each foreign income tax and each foreign payor. For this purpose, a series of CAAs occurring as part of a plan (referred to in the regulations as an ''aggregated CAA transaction'') are treated as a single CAA. The proposed regulations contain examples illustrating the scope of the foreign basis election.

The election is made by using foreign basis to determine the basis differences for purposes of computing a disqualified tax amount and an aggregate basis difference carryover. The election generally must be reflected on a timely filed original federal income tax return for the first U.S. taxable year that the foreign basis election is relevant. Proposed § 1.901(m)–4(c)(5) provides an exception for certain cases in which the RFA owner (U.S.) is a partnership. This exception generally provides relief when one or more partners and the partnership have agreed that the partnership would determine whether to provide the partners with information to apply section 901(m) based on foreign basis and, in fact, the partnership provided the information to the partner using foreign basis, but when the partner timely filed its tax return it failed to report the application of section 901(m). The purpose of the relief is to address situations in which a partner must file an amended return in order to properly reflect the application of section 901(m) but does not have access to the necessary information to apply section 901(m) using U.S. basis. The criteria for qualifying for this relief should prevent partners from using hindsight in determining whether to make the foreign basis election.

Proposed § 1.901(m)–4(c)(6) provides another exception to the requirement to make the election in a timely filed original federal income tax return that applies if a taxpayer chooses to consistently apply these proposed regulations retroactively to all CAAs occurring before the regulations are issued in final form, including CAAs for which the taxpayer chooses not to make a foreign basis election. In this case, a foreign basis election may be reflected on a timely filed amended federal income tax return (or tax returns, as appropriate), provided that all amended returns are filed no later than one year following the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

VI. Basis Difference Taken Into Account

Section 1.901(m)–5 provides rules for determining the amount of basis difference with respect to an RFA that is taken into account in a given U.S. taxable year (referred to in the regulations as ''allocated basis difference''). This allocated basis difference is used to compute a disqualified tax amount for a U.S. taxable year. Basis difference is taken into account in two ways: under an applicable cost recovery method or as a result of a disposition of the RFA.

For purposes of the discussion under this section VI of the Explanation of Provisions section of the preamble, unless otherwise indicated, a reference to direct ownership of an interest in an entity refers to direct ownership for U.S. income tax purposes, which includes ownership through one or more disregarded entities. A reference to indirect ownership of an interest in an entity refers to ownership through one or more entities that are treated as fiscally transparent for U.S. income tax purposes, at least one of which is not a disregarded entity. Finally, a reference to indirect ownership of an interest in an entity for foreign income tax purposes means ownership through one or more entities that are treated as fiscally transparent for foreign income tax purposes.

A. Cost Recovery Rules

1. Determining a Cost Recovery Amount

Proposed § 1.901(m)–5(b)(2)(i) incorporates by cross reference the general rule in the temporary regulations that a cost recovery amount for an RFA is determined by applying an applicable cost recovery method to the basis difference rather than to the U.S. basis of the RFA.

Proposed § 1.901(m)–5(b)(2)(ii) provides that if the entire U.S. basis of the RFA is not subject to the same cost recovery method, the applicable cost recovery method for determining the cost recovery amount is the cost recovery method that applies to the portion of the U.S. basis that corresponds to the basis difference.

Proposed § 1.901(m)–5(b)(3) provides that, for purposes of section 901(m), an applicable cost recovery method includes any method for recovering the cost of property over time for U.S. income tax purposes (each application of a method giving rise to a ''U.S. basis deduction''). Such methods include depreciation, amortization, or depletion, as well as a method that allows the cost (or a portion of the cost) of property to be expensed in the year of acquisition or in the placed-in-service year, such as under section 179. Applicable cost recovery methods do not include any provision allowing for the recovery of U.S. basis upon a disposition of an RFA.

2. Attributing or Allocating a Cost Recovery Amount to a Section 901(m) Payor

Under proposed § 1.901(m)–5(b)(1), when an RFA owner (U.S.) is a section 901(m) payor, all of the cost recovery amount is attributed to the section 901(m) payor and assigned to the U.S. taxable year of the section 901(m) payor in which the corresponding U.S. basis deduction with respect to the RFA is taken into account under the applicable cost recovery method. This is the case regardless of whether the deduction is deferred or disallowed under other Code provisions (for example, see section 263A, which requires the capitalization of certain costs and expenses).

If instead the RFA owner (U.S.) is not a section 901(m) payor but a fiscally transparent entity for U.S. income tax

purposes in which a section 901(m) payor directly or indirectly owns an interest, proposed § 1.901(m)–5(d)(2) allocates all or a portion of the cost recovery amount to the section 901(m) payor. Under those rules, a cost recovery amount is allocated to the section 901(m) payor to the extent the U.S. basis deduction that corresponds to the cost recovery amount (both of which are determined at the level of the RFA owner (U.S.)) is (or will be) included in the section 901(m) payor's distributive share of the income of the RFA owner (U.S.) for U.S. income tax purposes. Proposed § 1.901(m)–5(d)(6) assigns an allocated cost recovery amount to the U.S. taxable year of the section 901(m) payor that includes the last day of the U.S. taxable year of the RFA owner (U.S.) in which the RFA owner (U.S.) takes into account the corresponding U.S. basis deduction (without regard to whether the deduction is deferred or disallowed under other Code provisions).

Special rules under proposed § 1.901(m)–5(e), discussed in section VI.D of the Explanation of Provisions section of this preamble, allocate a cost recovery amount that arises from an RFA with respect to certain section 743(b) CAAs. In addition, special rules under proposed § 1.901(m)–5(g), discussed in section VI.F of the Explanation of Provisions section of this preamble, allocate a cost recovery amount to a section 901(m) payor in certain cases in which the RFA owner (U.S.) either is a reverse hybrid or is a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid. A reverse hybrid is an entity that is treated as a corporation for U.S. income tax purposes but as a fiscally transparent entity for foreign income tax purposes.

B. General Disposition Rules

1. Definition of Disposition and Determining a Disposition Amount

Proposed § 1.901(m)–1(a)(10) defines (by cross reference to the temporary regulations) a disposition for purposes of section 901(m) as an event that results in gain or loss being recognized with respect to an RFA for purposes of U.S. income tax, a foreign income tax, or both. Proposed § 1.901(m)–5(c)(2) incorporates by cross reference the rules provided in the temporary regulations for determining the amount of basis difference taken into account upon a disposition of an RFA (the disposition amount). Section 1.901(m)–5T(c)(2) provides that, if a disposition of an RFA is fully taxable for U.S. and foreign income tax purposes, the disposition amount will be any remaining unallocated basis difference (positive or negative). Section 1.901(m)–5T(c)(2) further provides that, if a disposition of an RFA is not fully taxable for both U.S. and foreign income tax purposes and the RFA has a *positive* basis difference, the disposition amount is based solely on the amount, if any, of foreign disposition gain and U.S. disposition loss. If, on the other hand, a disposition of an RFA is not fully taxable for both U.S. and foreign income tax purposes and the RFA has a *negative* basis difference, the temporary regulations provide that the disposition amount is based solely on the amount, if any, of foreign disposition loss and U.S. disposition gain. See section V.B of the preamble to the temporary regulations for a further discussion of these provisions.

2. Attributing or Allocating a Disposition Amount to a Section 901(m) Payor

Under proposed § 1.901(m)–5(c)(1), when the RFA owner (U.S.) is a section 901(m) payor, all of the disposition amount is attributed to the section 901(m) payor and assigned to the U.S. taxable year of the section 901(m) payor in which the disposition occurs.

If instead the RFA owner (U.S.) is not a section 901(m) payor but a fiscally transparent entity for U.S. income tax purposes in which a section 901(m) payor directly or indirectly owns an interest, proposed § 1.901(m)–5(d), discussed in section VI.C of the Explanation of Provisions section of this preamble, allocates all or a portion of a disposition amount to the section 901(m) payor and assigns it to a U.S. taxable year of the section 901(m) payor.

Special rules under proposed § 1.901(m)–5(e), discussed in section VI.D of the Explanation of Provisions section of this preamble, allocate a disposition amount to a section 901(m) payor and assign it to a U.S. taxable year of the section 901(m) payor when the disposition amount arises from an RFA with respect to certain section 743(b) CAAs. Special rules under proposed § 1.901(m)–5(f), discussed in section VI.E of the Explanation of Provisions section of this preamble, allocate a disposition amount attributable to foreign disposition gain or foreign disposition loss to a section 901(m) payor and assign it to a U.S. taxable year of the section 901(m) payor when there is a mid-year transaction. Special rules under proposed § 1.901(m)–5(g), discussed in section VI.F of the Explanation of Provisions section of this preamble, allocate a disposition amount to a section 901(m) payor and assign it to a U.S. taxable year of the section 901(m) payor in certain cases in which the RFA owner (U.S.) either is a reverse hybrid or is a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid.

C. Rules for Allocating and Assigning a Disposition Amount When the RFA Owner (U.S.) Is a Fiscally Transparent Entity

This section describes the rules for allocating a disposition amount to a section 901(m) payor when the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes in which a section 901(m) payor directly or indirectly owns an interest, as well as rules for assigning the allocated amount to a U.S. taxable year of the section 901(m) payor.

The allocation rules (discussed in sections VI.C.1 and 2 of the Explanation of Provisions section of this preamble) vary depending on whether the disposition amount is attributable to foreign disposition gain or loss or U.S. disposition gain or loss. The rules for determining the extent to which a disposition amount is attributable to foreign or U.S. disposition gain or loss are discussed in section VI.C.3 of the Explanation of Provisions section of this preamble. The rules for assigning allocated disposition amounts to a U.S. taxable year of a section 901(m) payor are discussed in section VI.C.4 of the Explanation of Provisions section of this preamble.

1. Allocation of a Disposition Amount Attributable to Foreign Disposition Gain or Foreign Disposition Loss

Proposed § 1.901(m)–5(d)(3) addresses the allocation of a disposition amount attributable to foreign disposition gain or foreign disposition loss of an RFA. These rules should be interpreted and applied in a manner consistent with the principle that a disposition amount attributable to foreign disposition gain or foreign disposition loss should be allocated to a section 901(m) payor in the same proportion that the gain or loss is taken into account in computing a foreign income tax amount that is paid or accrued by, or considered paid or accrued by, the section 901(m) payor. This is because, for example, if an RFA has a positive basis difference, a disposition amount attributable to foreign disposition gain represents an amount of gain in years following the CAA that is included in foreign income but never included in U.S. taxable income or earnings and profits because of the step-up in the U.S. basis of the

RFA that occurred as a result of the CAA. Accordingly, to the extent a foreign disposition gain is taken into account in computing a foreign income tax amount, a portion of that foreign income tax amount should be disallowed as a foreign tax credit under section 901(m). Similarly, if an RFA has a negative basis difference and a foreign disposition loss is taken into account in computing a foreign income tax amount, this should result in an offset to the amount of the foreign income tax that otherwise would be disallowed as a foreign tax credit under section 901(m) as a result of a positive basis difference with respect to one or more other RFAs.

There are two separate rules for identifying the extent to which a foreign disposition gain or foreign disposition loss is taken into account in computing a foreign income tax amount that is paid or accrued by, or considered paid or accrued by, a section 901(m) payor that directly or indirectly owns an interest in an RFA owner (U.S.) that is a fiscally transparent entity for U.S. income tax purposes. The first rule, which is described in proposed § 1.901(m)–5(d)(3)(ii), applies when the foreign income tax amount is not allocated, for example, when the foreign payor is the section 901(m) payor. The second rule, which is described in proposed § 1.901(m)–5(d)(3)(iii), applies when the foreign income tax amount is allocated, for example, under § 1.704–1(b)(4)(viii) when the foreign payor is a partnership for U.S. income tax purposes in which the section 901(m) payor is a partner.

a. First Allocation Rule

The first allocation rule applies when a section 901(m) payor, or a disregarded entity directly owned by a section 901(m) payor, is a foreign payor whose foreign income includes a distributive share of the foreign income (that includes the foreign disposition gain or foreign disposition loss) of the RFA owner (foreign). In this structure, the entire foreign income tax amount reflected on the foreign income tax return of the foreign payor is paid or accrued by, or considered paid or accrued by, the section 901(m) payor. This will be the case when the RFA owner (U.S.) is treated as a fiscally transparent entity not just for U.S. income tax purposes, but also for foreign income tax purposes, and the section 901(m) payor directly or indirectly owns an interest in the RFA owner (U.S.), provided that, in the case of indirect ownership, any entities in the ownership chain between the section 901(m) payor and the RFA owner (U.S), or, when one or more disregarded entities are directly owned by the section 901(m) payor, between the lowest-tier disregarded entity and the RFA owner (U.S.), are fiscally transparent for both U.S. and foreign income tax purposes. In these cases, the RFA owner (U.S.) and the RFA owner (foreign) are the same entity, except in the unusual case where the RFA owner (U.S.) is an entity that is disregarded as separate from its owner for foreign income tax purposes.

The first allocation rule allocates a portion of a disposition amount attributable to foreign disposition gain or foreign disposition loss, as applicable, to the section 901(m) payor proportionally to the amount of the foreign disposition gain or foreign disposition loss that is included in the foreign payor's (in other words, the section 901(m) payor or the disregarded entity, as the case may be) distributive share of the foreign income of the RFA owner (foreign) for foreign income tax purposes.

The following example illustrates the first allocation rule. A domestic entity that is a corporation for both U.S. and foreign income tax purposes (corporate partner) directly owns, for both U.S. and foreign income tax purposes, an interest in a foreign entity that is a partnership for both U.S. and foreign income tax purposes and that is the RFA owner (U.S.) and the RFA owner (foreign). In this case, when the partnership recognizes foreign disposition gain with respect to an RFA, the foreign income tax amount with respect to such gain is paid by the partners on their distributive shares of the foreign income of the partnership that includes the foreign disposition gain. The corporate partner, and not the partnership, is therefore a foreign payor and a section 901(m) payor. Accordingly, under the first allocation rule, a disposition amount attributable to foreign disposition gain is allocated to the corporate partner proportionally to the amount of the foreign disposition gain that is included in the corporate partner's distributive share of the foreign income of the partnership. Thus, for example, if the partnership recognizes $100 of foreign disposition gain and 50 percent of that gain is included in the corporate partner's distributive share of the foreign income of the partnership, and the disposition amount attributable to the foreign disposition gain is $40, the corporate partner would be allocated $20 of that amount (50 percent of $40). The same result would apply if the corporate partner directly owned the partnership interest through a disregarded entity that is the foreign payor.

b. Second Allocation Rule

The second allocation rule applies when, instead of a section 901(m) payor or a disregarded entity directly owned by a section 901(m) being a foreign payor, a section 901(m) payor directly or indirectly owns an interest in a fiscally transparent entity for U.S. income tax purposes (other than a disregarded entity directly owned by the section 901(m) payor) that is a foreign payor whose foreign income includes all or a portion of the foreign income (that includes the foreign disposition gain or foreign disposition loss) of the RFA owner (foreign). Therefore, the section 901(m) payor is considered to pay or accrue only an allocated portion of the foreign income tax amount reflected on the foreign income tax return of the foreign payor. This will be the case when a section 901(m) payor directly or indirectly owns an interest in the foreign payor, and the foreign payor is (i) the RFA owner (U.S.), (ii) another fiscally transparent entity for U.S. income tax purposes (other than a disregarded entity directly owned by a section 901(m) payor) that directly or indirectly owns an interest in the RFA owner (U.S.) for both U.S. and foreign income tax purposes, or (iii) a disregarded entity directly owned by the RFA owner (U.S.). In each of these cases, the entity subject to tax for purposes of the foreign income tax (that is, the foreign payor) is treated as a fiscally transparent entity for U.S. income tax purposes.

The mechanics of the second allocation rule are different than those of the first allocation rule. This is because the second allocation rule applies when neither the section 901(m) payor, nor a disregarded entity directly owned by a section 901(m) payor, is a foreign payor that takes into account a foreign disposition gain or foreign disposition loss for purposes of calculating a foreign income tax amount, but instead, for U.S. income tax purposes, a foreign income tax amount of the foreign payor is allocated to, and considered paid or accrued by, the section 901(m) payor. Accordingly, the second allocation rule allocates a portion of a disposition amount attributable to foreign disposition gain or foreign disposition loss, as applicable, to the section 901(m) payor proportionally to the amount of the foreign disposition gain or foreign disposition loss that is included in the allocable foreign income of the section 901(m) payor. As described in section IV.A of the Explanation of Provisions section of this preamble, allocable foreign income is generally the portion

of foreign income of a foreign payor that relates to the portion of the foreign income tax amount of that foreign payor that is allocated to and considered paid or accrued by a section 901(m) payor.

The following example illustrates the second allocation rule. A domestic entity that is a corporation for both U.S. and foreign income tax purposes (corporate partner) directly owns an interest in a foreign entity, the RFA owner (U.S.) and RFA owner (foreign), that is a partnership for U.S. income tax purposes but a corporation for purposes of a foreign income tax (a hybrid partnership). In this case, when the hybrid partnership recognizes foreign disposition gain with respect to an RFA, it is the hybrid partnership, rather than the partners, that takes the gain into account for purposes of calculating a foreign income tax amount. The hybrid partnership is therefore the foreign payor. For U.S. income tax purposes, a foreign income tax amount of the hybrid partnership is allocated to, and considered paid or accrued by, its partners, including the corporate partner that is a section 901(m) payor (see §§ 1.702–1(a)(6), 1.704–1(b)(4)(viii), and 1.901–2(f)(4)(i)). Under the second allocation rule, a disposition amount attributable to foreign disposition gain is allocated to the corporate partner proportionally to the amount of the foreign disposition gain that is included in the corporate partner's allocable foreign income. Thus, for example, if the hybrid partnership pays a foreign income tax amount of $30 on $200 of foreign income that includes $100 of foreign disposition gain and $15 of the foreign income tax amount (50 percent of $30) is allocated to and considered paid by the corporate partner, the corporate partner's allocable foreign income would be $100 (50 percent of the $200 foreign income to which the foreign income tax amount relates), which would include $50 of foreign disposition gain (50 percent of $100). If the disposition amount attributable to the foreign disposition gain is $60, the corporate partner would be allocated $30 of that amount ($60 multiplied by 50 percent, the portion of the total foreign disposition gain that is included in the corporate partner's allocable foreign income).

In this example, the analysis would be similar if the corporate partner instead indirectly owned the partnership interest (for example through an upper-tier partnership), because the corporate partner would continue to be the section 901(m) payor and the hybrid partnership would continue to be the RFA owner (U.S.), the RFA owner (foreign), and the foreign payor.

2. Allocation of a Disposition Amount Attributable to U.S. Disposition Gain or U.S. Disposition Loss

Proposed § 1.901(m)–5(d)(4) addresses the allocation of a disposition amount attributable to U.S. disposition gain or U.S. disposition loss. Such disposition amounts are allocated to a section 901(m) payor based on the portion of the U.S. disposition gain or U.S. disposition loss (which are determined at the level of the RFA owner (U.S.)) that is (or will be) included in the section 901(m) payor's distributive share of the income of the RFA owner (U.S.) for U.S. income tax purposes.

3. Determining the Extent to Which a Disposition Amount Is Attributable to Foreign or U.S. Disposition Gain or Loss

a. Positive Basis Difference

When an RFA has a positive basis difference, a disposition amount arises from a disposition of the RFA only if the disposition results in a foreign disposition gain or a U.S. disposition loss (or both). To allocate such a disposition amount to a section 901(m) payor, it is necessary to determine the extent to which the disposition amount is attributable to foreign disposition gain or U.S. disposition loss.

Proposed § 1.901(m)–5(d)(5)(i) provides that if the disposition results in either a foreign disposition gain or a U.S. disposition loss, but not both, the entire disposition amount is attributable to foreign disposition gain or U.S. disposition loss, as applicable, even if the disposition amount exceeds the foreign disposition gain or the absolute value of the U.S. disposition loss. If the disposition results in both a foreign disposition gain and a U.S. disposition loss, the disposition amount is attributable first to foreign disposition gain to the extent thereof, and the excess disposition amount, if any, is attributable to the U.S. disposition loss, even if the excess disposition amount exceeds the absolute value of the U.S. disposition loss. In the case of a disposition that is fully taxable for both U.S. and foreign income tax purposes, a disposition amount may exceed the sum of the foreign disposition gain and the absolute value of the U.S. disposition loss if, immediately before the CAA, the foreign basis in the RFA was greater than the U.S basis, and a foreign basis election was not made.

b. Negative Basis Difference

When an RFA has a negative basis difference, a disposition amount arises from a disposition of the RFA only if the disposition results in a foreign disposition loss or a U.S. disposition gain (or both). To allocate such a disposition amount to a section 901(m) payor, it is necessary to determine the extent to which the disposition amount is attributable to foreign disposition loss or U.S. disposition gain.

Proposed § 1.901(m)–5(d)(5)(ii) provides rules for making this determination when there is a negative basis difference that are similar to those provided in proposed § 1.901(m)–5(d)(5)(i) for a positive basis difference.

4. Assigning a Disposition Amount to a U.S. Taxable Year of a Section 901(m) Payor

When a disposition amount is allocated to a section 901(m) payor under proposed § 1.901(m)–5(d), proposed § 1.901(m)–5(d)(6) provides that the disposition amount is assigned to the U.S. taxable year of the section 901(m) payor that includes the last day of the U.S. taxable year of the RFA owner (U.S.) in which the disposition occurs.

D. Special Allocation Rules for Certain Section 743(b) CAAs

Proposed § 1.901(m)–5(e) provides that when a section 901(m) payor acquires a partnership interest in a section 743(b) CAA, including a section 743(b) CAA with respect to a lower-tier partnership that results from a direct acquisition by the section 901(m) payor of an interest in an upper-tier partnership, a cost recovery amount or a disposition amount that arises from an RFA with respect to that CAA is allocated to the acquiring section 901(m) payor. These amounts are assigned to the U.S. taxable year of the section 901(m) payor that includes the last day of the U.S. taxable year of the partnership in which, in the case of a cost recovery amount, the partnership takes into account the corresponding U.S. basis deduction, or, in the case of a disposition amount, the disposition occurs.

This special rule does not apply if it is another partnership, and not a section 901(m) payor, that acquires a partnership interest in a section 743(b) CAA. In that case, the general rules for allocating a cost recovery amount or disposition amount when the RFA owner (U.S.) is a fiscally transparent entity apply.

E. Special Allocation Rules for Certain Mid-Year Transactions

Proposed § 1.901(m)–5(f) provides rules for allocating a disposition amount when there is a disposition of an RFA during a foreign taxable year in which the foreign payor is involved in a mid-year transaction, and the disposition

results in foreign disposition gain or foreign disposition loss that is allocated under the principles of § 1.1502–76(b) to the persons involved in the mid-year transaction for purposes of allocating the foreign income tax amount of the foreign payor. A typical example is when a section 901(m) payor owns a disregarded entity that is both an RFA owner (foreign) and the foreign payor, and the disregarded entity sells the RFA in the same year that the section 901(m) payor sells the disregarded entity to another section 901(m) payor. If the RFA has positive unallocated basis difference and there is foreign disposition gain on the sale of the RFA, the sale will give rise to a disposition amount that will be used by the section 901(m) payors to calculate a disqualified portion of the foreign income tax amount reflected on the foreign income tax return of the disregarded entity. Pursuant to § 1.901–2(f)(4)(ii), that foreign income tax amount must be allocated between the buyer and seller of the disregarded entity based on the respective portions of foreign income that are attributable under the principles of § 1.1502–76(b) to the buyer's and seller's respective periods of ownership of the disregarded entity during its foreign taxable year. Under proposed § 1.901(m)–5(f)(2), the disposition amount attributable to foreign disposition gain is similarly allocated between the buyer and the seller based on the principles in proposed § 1.901(m)–5(d), discussed in section VI.C of the Explanation of Provisions section of this preamble, that apply to allocate a disposition amount when the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes.

F. Special Allocation Rules for Certain Reverse Hybrids

Proposed § 1.901(m)–5(g) addresses the allocation of cost recovery amounts and disposition amounts when the RFA owner (U.S.) is either a reverse hybrid or a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid for U.S. and foreign income tax purposes, and in either case, a foreign payor directly or indirectly owns an interest in the reverse hybrid for foreign income tax purposes and therefore includes in its foreign income a distributive share of the foreign income (that includes the foreign disposition gain or foreign disposition loss) of the RFA owner (foreign). These allocation rules are similar to the allocation rules discussed in section VI.C.1 of the Explanation of Provisions section of this preamble that apply to allocate a disposition amount attributable to foreign disposition gain or foreign disposition loss when the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes. These rules are broader in scope, however, because they apply to allocate not just foreign disposition gain or foreign disposition loss, but rather, both cost recovery amounts and entire disposition amounts (which may be attributable, in whole or in part, to U.S. disposition gain or U.S. disposition loss). This is because the basis difference giving rise to such amounts may not be taken into account in computing U.S. taxable income or earnings and profits of the owners of the reverse hybrid until one or more subsequent U.S. taxable years (for example, upon the receipt of a distribution of property from the reverse hybrid).

These rules should be interpreted and applied in a manner consistent with the principle that a cost recovery amount or a disposition amount (or both) should be allocated to a section 901(m) payor proportionally to the amount of the foreign income of the RFA owner (foreign) that is taken into account in computing a foreign income tax amount of a foreign payor that is paid or accrued by, or considered paid or accrued by, the section 901(m) payor.

There are two separate rules for allocating a cost recovery amount or disposition amount to a section 901(m) payor when the RFA owner (U.S.) either is a reverse hybrid or a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid for U.S. and foreign income tax purposes. The first rule, which is described in § 1.901(m)–5(g)(2), applies when the foreign income tax amount is not allocated, for example, when the foreign payor is the section 901(m) payor. The second rule, which is described in § 1.901(m)–5(g)(3), applies when the foreign income tax amount is allocated, for example, under § 1.704–1(b)(4)(viii) when the foreign payor is a partnership for U.S. income tax purposes in which the section 901(m) payor is a partner.

1. First Allocation Rule

The first allocation rule applies when a section 901(m) payor, or a disregarded entity directly owned by a section 901(m) payor, is the foreign payor whose foreign income includes a distributive share of the foreign income of the RFA owner (foreign). In this structure, the entire foreign income tax amount reflected on the foreign income tax return of the foreign payor is paid or accrued by, or considered paid or accrued by, the section 901(m) payor. This will be the case when a section 901(m) payor directly or indirectly owns an interest in the reverse hybrid, provided that in the case of indirect ownership, any entities in the ownership chain between the section 901(m) payor and the reverse hybrid, or, when one or more disregarded entities are directly owned by the section 901(m) payor, between the lowest-tier disregarded entity and the reverse hybird, are fiscally transparent for both U.S. and foreign income tax purposes. In these cases, the RFA owner (U.S.) and the RFA owner (foreign) are the same entity, except in the unusual case where the RFA owner (U.S.) is an entity that is disregarded as separate from its owner for foreign income tax purposes.

The first allocation rule allocates a portion of a cost recovery amount or a disposition amount to the section 901(m) payor proportionally to the amount of the foreign income of the RFA owner (foreign) that is included in the foreign income of the foreign payor (in other words, the section 901(m) payor or the disregarded entity, as the case may be).

The following example illustrates the first allocation rule. A domestic entity that is a corporation for both U.S. and foreign income tax purposes (corporate owner) owns an interest in a reverse hybrid that is the RFA owner (U.S.) and the RFA owner (foreign). A foreign income tax amount with respect to the foreign income of the reverse hybrid is paid by the owners of the reverse hybrid on their distributive shares of such foreign income. The corporate owner, and not the reverse hybrid, is therefore a foreign payor and a section 901(m) payor. Under the first allocation rule, a cost recovery amount or a disposition amount is allocated to the corporate owner proportionally to the amount of the foreign income of the reverse hybrid that is included in the foreign income of the corporate owner. Thus, for example, if 50 percent of the foreign income of the reverse hybrid is included in the foreign income of the corporate owner, the corporate owner would be allocated 50 percent of a cost recovery amount or a disposition amount with respect to an RFA owned by the reverse hybrid. The same result would apply if the corporate owner directly owned the interest in the reverse hybrid through a disregarded entity that is the foreign payor.

Alternatively, if the reverse hybrid was not the RFA owner (foreign) but instead the reverse hybrid owned an interest in the RFA owner (U.S.) and RFA owner (foreign), which is a partnership for both U.S. and foreign

income tax purposes, and 60 percent of the foreign income of the partnership is included in the foreign income of the reverse hybrid (and therefore 30 percent (50 percent of 60 percent) of the foreign income of the partnership is included in the foreign income of the corporate owner), the corporate owner would be allocated 30 percent of a cost recovery amount or a disposition amount with respect to an RFA owned by the partnership.

2. Second Allocation Rule

The second allocation rule applies when instead of a section 901(m) payor, or a disregarded entity directly owned by a section 901(m) payor, being a foreign payor, a section 901(m) payor directly or indirectly owns an interest in the foreign payor whose foreign income includes a distributive share of the foreign income of the RFA owner (foreign). Therefore, the section 901(m) payor is considered to pay or accrue only an allocated portion of the foreign income tax amount reflected on the foreign income tax return of the foreign payor. This will be the case when the foreign payor is a fiscally transparent entity for U.S. income tax purposes (other than a disregarded entity directly owned by the section 901(m) payor) that either directly or indirectly owns an interest in the RFA owner (foreign) for foreign income tax purposes. In these cases, the RFA owner (U.S.) and the RFA owner (foreign) are the same entity, except in the unusual case where the RFA owner (U.S.) is an entity that is disregarded as separate from its owner for foreign income tax purposes.

The mechanics of the second allocation rule are different than those of the first allocation rule. This is because the second allocation rule applies when neither a section 901(m) payor, nor a disregarded entity directly owned by a section 901(m) payor, is a foreign payor that takes into account the foreign income of the RFA owner (foreign) for purposes of calculating a foreign income tax amount, but instead, for U.S. income tax purposes, a foreign income tax amount of the entity that is the foreign payor is allocated to, and considered paid or accrued by, the section 901(m) payor. Accordingly, the second allocation rule allocates a portion of cost recovery amounts and disposition amounts proportionally to the amount of the foreign income of the RFA owner (foreign) that is included in the foreign income of the foreign payor that is then included in the allocable foreign income of the section 901(m) payor. As described in section IV.A of the Explanation of Provisions section of this preamble, allocable foreign income is generally the portion of foreign income of a foreign payor that relates to the portion of the foreign income tax amount of that foreign payor that is allocated to and considered paid or accrued by a section 901(m) payor.

The following example illustrates the second allocation rule. A domestic entity that is a corporation for both U.S. and foreign income tax purposes (corporate partner) owns an interest in an entity that is a partnership for U.S. income tax purposes but a corporation for foreign income tax purposes (hybrid partnership), which, in turn, owns an interest in a reverse hybrid that is the RFA owner (U.S.) and the RFA owner (foreign). A foreign income tax amount with respect to the foreign income of the reverse hybrid is paid by the owners of the reverse hybrid on their distributive shares of such foreign income. Therefore, the hybrid partnership, rather than its partners, is the foreign payor. For U.S. income tax purposes, the foreign income tax amount paid or accrued by the hybrid partnership is allocated to, and considered paid or accrued by, the corporate partner that is the section 901(m) payor (see §§ 1.702–1(a)(6), 1.704–1(b)(4)(viii), and 1.901–2(f)(4)(i)). Under the second allocation rule, a cost recovery amount or a disposition amount with respect to an RFA owned by the reverse hybrid is allocated to the corporate partner proportionally to the amount of foreign income of the reverse hybrid that is taken into account in determining the foreign income of the hybrid partnership and then the allocable foreign income of the corporate partner. Thus, for example, if the reverse hybrid has $500 of foreign income and the hybrid partnership pays a foreign income tax amount of $30 on $200 of foreign income that includes a $100 distributive share of the foreign income of the reverse hybrid (20 percent of $500) and $15 of the foreign income tax amount (50 percent of $30) is allocated to and considered paid by the corporate partner, then the corporate partner's allocable foreign income would be $100 (50 percent of the $200 foreign income to which the foreign income tax amount relates). A cost recovery amount or disposition amount with respect to the RFAs owned by the reverse hybrid would be allocated 10 percent to the corporate partner (the corporate partner's 50 percent share of the hybrid partnership's 20 percent share of the reverse hybrid's foreign income).

VII. Successor Rules

Proposed § 1.901(m)–6 provides successor rules for applying section 901(m) following a transfer of RFAs that have basis difference that has not yet been fully taken into account (referred to in the regulations as ''unallocated basis difference'') as well as for determining when an aggregate basis difference carryover of a section 901(m) payor either becomes an aggregate basis difference carryover of the section 901(m) payor with respect to another foreign payor or is transferred to another section 901(m) payor.

A. Unallocated Basis Difference

Proposed § 1.901(m)–6(b)(1) and (2) incorporate by cross reference the successor rules set forth in the temporary regulations, which provide generally that section 901(m) continues to apply to an RFA after it has been transferred for U.S. income tax purposes if the RFA continues to have unallocated basis difference following the transfer (a successor transaction).

Proposed § 1.901(m)–6(b)(3) sets forth two clarifications for applying the successor rules. First, if an asset is an RFA with respect to more than one foreign income tax, the successor rules apply separately with respect to each foreign income tax. Second, any subsequent cost recovery amount for an RFA transferred in a successor transaction will be determined based on the applicable cost recovery method that applies to the U.S. basis (or portion thereof) that corresponds to the unallocated basis difference. Thus, if a successor transaction restarts the depreciation schedule for an RFA, the transaction may result in unallocated basis difference being taken into account at a different recovery rate than otherwise would have applied.

Proposed § 1.901(m)–6(b)(4)(iii) also incorporates by cross reference the rule set forth in the temporary regulations that provides an exception to the general rule when an RFA is subject to multiple section 743(b) CAAs. See section VI.B. of the Explanation of Provisions section of the preamble to the temporary regulations for a discussion of those provisions.

Proposed § 1.901(m)–6(b)(4)(ii), which is not included in the temporary regulations, provides an exception to the general successor rule if a foreign basis election is made under proposed § 1.901(m)–4(c) with respect to a subsequent CAA that otherwise would trigger the rules for successor transactions. If a foreign basis election is made with respect to a foreign income tax, the only basis difference that will be taken into account after the subsequent CAA with respect to that foreign income tax is the basis difference determined for the subsequent CAA.

B. Aggregate Basis Difference Carryover

Proposed § 1.901(m)–6 provides successor rules for aggregate basis difference carryovers, the computation of which is described in section IV.B of the Explanation of Provisions section of this preamble. An aggregate basis difference carryover is treated as a tax attribute of the section 901(m) payor that retains its character as an aggregate basis difference carryover with respect to a foreign income tax and a foreign payor and with respect to a separate category, as described in § 1.904–4(m) (including the section 904(d) categories). When a section 901(m) payor transfers its assets in a transaction to which section 381 applies, proposed § 1.901(m)–6(c)(1) provides that any aggregate basis difference carryovers of the section 901(m) payor are transferred to the corporation that succeeds to the earnings and profits, if any. When substantially all of the assets of one foreign payor are transferred to another foreign payor, both of which are directly or indirectly owned by the same section 901(m) payor, proposed § 1.901(m)–6(c)(2) provides that an aggregate basis difference carryover of the section 901(m) payor with respect to the transferor foreign payor becomes an aggregate basis difference carryover of the section 901(m) payor with respect to the transferee foreign payor.

Proposed § 1.901(m)–6(c)(3) provides an anti-abuse rule that would transfer an aggregate basis difference carryover when, with a principal purpose of avoiding the application of section 901(m), there is a transfer of assets or a change in either the allocation of foreign income for foreign income tax purposes or the allocation of foreign income tax amounts for U.S. income tax purposes that is intended to separate foreign income tax amounts from the related aggregate basis difference carryover. This anti-abuse rule would apply, for example, if, with the principal purpose of avoiding the application of section 901(m), a partnership agreement is amended in order to reduce the allocation of foreign income to a partner that is a section 901(m) payor with an aggregate basis difference carryover.

VIII. De Minimis Rules

Proposed § 1.901(m)–7 describes de minimis rules under which certain basis differences are not taken into account for purposes of section 901(m). This determination is made when an asset subject to a CAA first becomes an RFA. If that same asset is also an RFA by reason of being subject to a subsequent CAA, the de minimis tests are applied only to the additional basis difference, if any, that results from the subsequent CAA. Accordingly, any unallocated basis difference that arose from the prior CAA that did not qualify for the de minimis exemption at the time of the prior CAA will not be retested at the time of the subsequent CAA.

In general, a basis difference with respect to an RFA is not taken into account for purposes of section 901(m) if either (i) the sum of the basis differences for all RFAs with respect to the CAA is less than the greater of $10 million or 10 percent of the total U.S. basis of all RFAs immediately after the CAA; or (ii) the RFA is part of a class of RFAs for which the sum of the basis differences of all RFAs in the class is less than the greater of $2 million or 10 percent of the total U.S. basis of all RFAs in the class. For this purpose, the classes of RFAs are the seven asset classes defined in § 1.338–6(b).

The Treasury Department and the IRS decided that transactions between related parties should be more tightly regulated, and therefore, the threshold dollar amounts and percentages to meet the de minimis exemptions for related party CAAs are lower than those for unrelated party CAAs, replacing the terms ''$10 million,'' ''10 percent,'' and ''$2 million'' wherever they occur with the terms ''$5 million,'' ''5 percent,'' and ''$1 million,'' respectively. In addition, an anti-abuse provision at proposed § 1.901(m)–7(e) denies application of the de minimis exemptions to CAAs between related parties that are entered into or structured with a principal purpose of avoiding the application of section 901(m).

IX. Miscellaneous

Proposed § 1.901(m)–8(b) provides that, when a foreign corporation becomes a section 902 corporation for the first time, as part of the required reconstruction of the U.S. tax history of the pre-1987 foreign income taxes of the foreign corporation, section 901(m) and these regulations must be applied to determine any disqualified tax amounts or aggregate basis difference carryovers that apply to the foreign corporation.

Proposed § 1.901(m)–8(c) provides an anti-abuse rule that applies to disregard an RFA with a built-in loss to the extent it relates to any asset acquisition structured with a principal purpose to use that RFA to avoid the application of section 901(m). This rule may apply, for example, if, with a principal purpose of avoiding the application of section 901(m), an asset is acquired in a transaction that preserves a built-in loss in the asset for U.S. income tax purposes but not for foreign income tax purposes.

X. Modifications to the Section 704(b) Regulations Related to Section 901(m)

Section 1.704–1(b)(4)(viii) provides a safe harbor under which allocations of creditable foreign tax expenditures (CFTEs) (as defined in § 1.704–1(b)(4)(viii)(*b*)) by a partnership to its partners are deemed to be in accordance with the partners' interests in the partnership. In general, the purpose of the safe harbor is to match allocations of CFTEs with the income to which the CFTEs relate. In order to apply the safe harbor, a partnership must (1) determine the partnership's ''CFTE categories,'' (2) determine the partnership's net income in each CFTE category, and (3) allocate the partnership's CFTEs to each category. In order to satisfy the safe harbor, partnership allocations of CFTEs in a CFTE category must be proportionate to the allocations of the partnership's net income in the CFTE category.

A CFTE may be subject to section 901(m) because it is a foreign income tax amount that is paid or accrued by a partnership. Specifically, if a partnership owns an RFA with respect to a foreign income tax and that RFA has a basis difference subject to section 901(m), a portion of a foreign income tax amount paid or accrued by the partnership that relates to that foreign income tax may be disallowed as a foreign tax credit under section 901(m) in the hands of section 901(m) payors to whom the foreign income tax amount is allocated. The disqualified tax amount is determined by taking into account cost recovery amounts and disposition amounts with respect to the RFA that are allocated to those section 901(m) payors pursuant to the rules provided in proposed § 1.901(m)–5. In order to ensure that the proper portion of a foreign income tax amount paid or accrued by a partnership is disallowed under section 901(m), adjustments to the net income (and the allocations of that income) in a CFTE category that includes items attributable to the RFA are necessary in certain cases.

To illustrate such a case, assume a domestic entity that is a partnership for U.S. income tax purposes but a corporation for purposes of a foreign income tax (a hybrid partnership) is owned by partner A and partner B, each of which is a domestic entity that is a corporation for both U.S. and foreign income tax purposes. In this case, the hybrid partnership is the foreign payor and partners A and B are section 901(m) payors. The hybrid partnership is the RFA owner (U.S.) and the RFA owner (foreign) with respect to a single asset that is an RFA. Assume that in a given

year the hybrid partnership has 110u of gross income for both U.S. and foreign tax purposes and a 10u depreciation deduction solely for U.S. income tax purposes, which gives rise to a cost recovery amount with respect to the RFA (as determined under proposed § 1.901(m)–5(b)(2)). All partnership items are allocated equally to partners A and B, except that the entire 10u U.S. depreciation deduction is allocated to partner A. Thus, partner A's distributive share of income is 45u (110u × 50%, less 10u) and partner B's distributive share of income is 55u (110u × 50%). Because the entire U.S. depreciation deduction is (or will be included) in partner A's distributive share of income for U.S. income tax purposes, the entire cost recovery amount that corresponds to the U.S. depreciation deduction of 10u is allocated to partner A. See proposed § 1.901(m)–5(d)(2). As a result, Partner A will take into account the 10u cost recovery amount in calculating a disqualified tax amount with respect to the portion of the relevant foreign income tax amount paid or accrued by the hybrid partnership and allocated to partner A under the CFTE allocation rules. In order to ensure that the portion of the foreign income tax amount paid or accrued by the hybrid partnership that is attributable to the 10u basis difference is properly subject to section 901(m), the U.S. depreciation deduction should not be taken into account under the CFTE allocation rules so that the portion of the foreign income tax amount attributable to the 10u basis difference is allocated to partner A. Accordingly, the net income of the CFTE category that includes the U.S. basis deduction should be increased by 10u (from 100u to 110u) to back out the portion of the U.S. depreciation deduction that corresponds to the cost recovery amount, and partner A's share of that net income should be increased by 10u (from 45u to 55u). In this example, as a result of the adjustment, the foreign income tax amount paid or accrued by the hybrid partnership will be allocated equally between partner A and partner B, because they each will have a 50-percent share of the net income in the CFTE category, as adjusted. Absent the adjustment, a portion of the foreign income tax amount attributable to the 10u basis difference would be allocated to partner B, a person that is not subject to section 901(m) (because no cost recovery amount is allocated to partner B).

No modification to the safe harbor is necessary to address cost recovery amounts and disposition amounts attributable to section 743(b) adjustments that are allocated to partners under proposed § 1.901(m)–5(e) (which applies when a section 901(m) payor acquires a partnership interest in a section 743(b) CAA), because, in these cases, § 1.704–1T(b)(4)(viii)(*c*)(*3*)(*i*) already provides that the partnership determines net income in a CFTE category without regard to section 743(b) adjustments that its partners may have to the basis of property of the partnership. However, as discussed in section VI.D of the Explanation of Provisions section of this preamble, proposed § 1.901(m)–5(e) does not apply when another partnership (which by definition cannot be a section 901(m) payor) acquires a partnership interest in a section 743(b) CAA. Thus, modification to the safe harbor is necessary for all CAAs other than those section 743(b) CAAs described in proposed § 1.901(m)–5(e).

Accordingly, these proposed regulations add special rules under proposed § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*), (*vi*), and (*vii*) to address partnership items that give rise to cost recovery amounts and disposition amounts attributable to CAAs (other than section 743(b) CAAs described in proposed § 1.901(m)–5(e)). Specifically, these rules provide that, if an RFA has a positive basis difference, net income in a CFTE category that takes into account partnership items of income, deduction, gain, or loss attributable to the RFA (applicable CFTE category) is increased by the sum of the cost recovery amounts and disposition amounts attributable to U.S. disposition loss that correspond to those partnership items. Furthermore, to the extent a partner is allocated those cost recovery amounts or disposition amounts attributable to U.S. disposition loss, that partner's share of the net income in the CFTE category is increased by the same amount. Alternatively, if an RFA has a negative basis difference, the net income in the applicable CFTE category is decreased by the sum of the cost recovery amounts and disposition amounts attributable to U.S. disposition gain that correspond to partnership items in that CFTE category. Furthermore, to the extent a partner is allocated those cost recovery amounts or disposition amounts attributable to U.S. disposition gain, that partner's share of the net income in the CFTE category is decreased by the same amount.

XI. Effective/Applicability Dates

These proposed regulations will apply to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. Taxpayers may, however, rely on the proposed regulations prior to the date the regulations are applicable provided that they both consistently apply proposed § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016 and consistently apply proposed § 1.901(m)–1 and §§ 1.901(m)–3 through 1.901(m)–8 (excluding § 1.901(m)–4(e)) to all CAAs occurring on or after January 1, 2011. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply because the regulations do not impose a collection of information on small entities. Pursuant to section 7805(f), these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under **ADDRESSES**. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Jeffrey L. Parry of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Sections 1.901(m)–1 through –8 also issued under 26 U.S.C. 901(m)(7).* * *

Section 1.901(m)–5 also issued under 26 U.S.C. 901(m)(3)(B)(ii). * * *

■ **Par. 2.** Section 1.704–1, as proposed to be amended at 81 FR 5967, February 4, 2016, is further amended by adding two sentences at the end of paragraph (b)(1)(ii)(b)(*1*) and by adding paragraphs (b)(4)(viii)(*c*)(*4*)(*v*) through (b)(4)(viii)(*c*)(*4*)(*vii*) to read as follows:

§ 1.704–1 Partner's distributive share.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(*b*) * * *

(*1*) * * * Paragraphs (b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*) of this section apply to covered asset acquisitions (CAAs) (as defined in § 1.901(m)–1(a)(8)) occurring on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. Taxpayers may, however, rely on paragraphs (b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*) of this section prior to the date paragraphs (b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*) of this section are applicable provided that they consistently apply paragraphs (b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*) of this section, § 1.901(m)–1, and §§ 1.901(m)–3 through 1.901(m)–8 (excluding § 1.901(m)–4(e)) to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after *December 7, 2016.*

* * * * *

(4) * * *

(viii) * * *

(*c*) * * *

(*4*) * * *

(*v*) *Adjustments related to section 901(m).* If one or more assets owned by a partnership are relevant foreign assets (or RFAs) with respect to a foreign income tax, then, solely for purposes of applying the safe harbor provisions of paragraph (b)(4)(viii)(*a*)(*1*) of this section to allocations of CFTEs with respect to that foreign income tax, the net income in a CFTE category that includes partnership items of income, deduction, gain, or loss attributable to the RFA shall be increased by the amount described in paragraph (b)(4)(viii)(*c*)(*4*)(*vi*) of this section and reduced by the amount described in paragraph (b)(4)(viii)(*c*)(*4*)(*vii*) of this section. Similarly, a partner's CFTE category share of income shall be increased by the portion of the amount described in paragraph (b)(4)(viii)(*c*)(*4*)(*vi*) of this section that is allocated to the partner under § 1.901(m)–5(d) and reduced by the portion of the amount described in paragraph (b)(4)(viii)(*c*)(*4*)(*vii*) of this section that is allocated to the partner under § 1.901(m)–5(d). The principles of this paragraph (b)(4)(viii)(*c*)(*4*)(*v*) apply similarly when a partnership owns an RFA indirectly through one or more other partnerships. For purposes of paragraphs (b)(4)(viii)(*c*)(*4*)(*v*), (b)(4)(viii)(*c*)(*4*)(*vi*), and (b)(4)(viii)(*c*)(*4*)(*vii*) of this section, basis difference is defined in § 1.901(m)–4, cost recovery amount is defined in § 1.901(m)–5(b)(2), disposition amount is defined in § 1.901(m)–5(c)(2), foreign income tax is defined in § 1.901(m)–1(a)(21), RFA is defined in § 1.901(m)–2(c), U.S. disposition gain is defined in § 1.901(m)–1(a)(43), and U.S. disposition loss is defined in § 1.901(m)–1(a)(44).

(*vi*) *Adjustment amounts for RFAs with a positive basis difference.* With respect to RFAs with a positive basis difference, the amount referenced in (b)(4)(viii)(*c*)(*4*)(*v*) is the sum of any cost recovery amounts and disposition amounts attributable to U.S. disposition loss that correspond to partnership items that are included in the net income in the CFTE category and that are taken into account for the U.S. taxable year of the partnership under § 1.901(m)–5(d).

(*vii*) *Adjustment amounts for RFAs with a negative basis difference.* With respect to RFAs with a negative basis difference, the amount referenced in (b)(4)(viii)(*c*)(*4*)(*v*) is the sum of any cost recovery amounts and disposition amounts attributable to U.S. disposition gain that correspond to partnership items that are included in the net income in the CFTE category and that are taken into account for the U.S. taxable year of the partnership under § 1.901(m)–5(d).

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■ **Par. 3.** Section 1.901(m)–1 is added to read as follows:

§ 1.901(m)–1 Definitions.

(a) *Definitions.* [The text of proposed § 1.901(m)–1(a) is the same as the text of § 1.901(m)–1T(a) published elsewhere in this issue of the **Federal Register**.]

(1) The term *aggregate basis difference* means, with respect to a foreign income tax and a foreign payor, the sum of the allocated basis differences for a U.S. taxable year of a section 901(m) payor, plus any aggregate basis difference carryover from the immediately preceding U.S. taxable year of the section 901(m) payor with respect to the foreign income tax and foreign payor, as adjusted under § 1.901(m)–6(c). For purposes of this definition, if foreign law imposes tax on the combined income (within the meaning of § 1.901–2(f)(3)(ii)) of two or more foreign payors, all foreign payors whose items of income, deduction, gain, or loss are included in the U.S. taxable income or earnings and profits of the section 901(m) payor are treated as a single foreign payor. Aggregate basis difference is determined with respect to each separate category described in § 1.904–4(m).

(2) The term *aggregate basis difference carryover* has the meaning provided in § 1.901(m)–3(c).

(3) The term *aggregated CAA transaction* means a series of related CAAs occurring as part of a plan.

(4) The term *allocable foreign income* means the portion of foreign income of a foreign payor that relates to the foreign income tax amount of the foreign payor that is paid or accrued by, or considered paid or accrued by, a section 901(m) payor.

(5) The term *allocated basis difference* means, with respect to an RFA and a foreign income tax, the sum of the cost recovery amounts and disposition amounts assigned to a U.S. taxable year of the section 901(m) payor under § 1.901(m)–5.

(6) through (8) [The text of proposed §§ 1.901(m)–1(a)(6) through (8) is the same as the text of §§ 1.901(m)–1T(a)(6) through (8) published elsewhere in this issue of the **Federal Register**.]

(9) The term *cumulative basis difference exemption* has the meaning provided in § 1.901(m)–7(b)(2).

(10) through (11) [The text of proposed §§ 1.901(m)–1(a)(10) through (11) is the same as the text of §§ 1.901(m)–1T(a)(10) through (11) published elsewhere in this issue of the **Federal Register**.]

(12) The term *disqualified tax amount* has the meaning provided in § 1.901(m)–3(b).

(13) through (14) [The text of proposed §§ 1.901(m)–1(a)(13) through (14) is the same as the text of §§ 1.901(m)–1T(a)(13) through (14) published elsewhere in this issue of the **Federal Register**.]

(15) The term *foreign basis* means the adjusted basis of an asset determined for purposes of a foreign income tax.

(16) The term *foreign basis election* has the meaning provided in § 1.901(m)–4(c).

(17) The term f*oreign country creditable tax* (or *FCCT*) means, with respect to a foreign income tax amount, the amount of income, war profits, or excess profits tax paid or accrued to a foreign country or possession of the United States and claimed as a foreign tax credit for purposes of determining the foreign income tax amount. To qualify as a FCCT, the tax imposed by the foreign country or possession must be a foreign income tax or a withholding tax determined on a gross basis as described in section 901(k)(1)(B).

(18) through (21) [The text of proposed §§ 1.901(m)–1(a)(18) through (21) is the same as the text of §§ 1.901(m)–1T(a)(18) through (21) published elsewhere in this issue of the **Federal Register**.]

(22) The term *foreign income tax amount* means, with respect to a foreign income tax, the amount of tax (including an amount of tax that is zero) reflected on a foreign tax return (as properly amended or adjusted). If foreign law imposes tax on the combined income (within the meaning of § 1.901–2(f)(3)(ii)) of two or more foreign payors, however, a foreign income tax amount means the amount of tax imposed on the combined income, regardless of whether the tax is reflected on a single foreign tax return.

(23) The term *foreign payor* means an individual or entity (including a disregarded entity) subject to a foreign income tax. If a foreign income tax imposes tax on the combined income (within the meaning of § 1.901–2(f)(3)(ii)) of two or more individuals or entities, each such individual or entity is a foreign payor. An individual or entity may be a foreign payor with respect to more than one foreign income tax for purposes of applying section 901(m).

(24) The term *foreign taxable year* means a taxable year for purposes of a foreign income tax.

(25) The term *mid-year transaction* means a transaction in which a foreign payor that is a corporation or a disregarded entity has a change in ownership or makes an election pursuant to § 301.7701–3 to change its entity classification, or a transaction in which a foreign payor that is a partnership terminates under section 708(b)(1), provided in each case that the foreign payor's foreign taxable year does not close as a result of the transaction, and, if the foreign payor is a corporation or a partnership, the foreign payor's U.S. taxable year closes.

(26) through (28) [The text of proposed §§ 1.901(m)–1(a)(26) through (28) is the same as the text of §§ 1.901(m)–1T(a)(26) through (28) published elsewhere in this issue of the **Federal Register**.]

(29) The term *reverse hybrid* has the meaning provided in § 1.909–2(b)(1)(iv).

(30) The term *RFA class exemption* has the meaning provided in § 1.901(m)–7 (b)(3).

(31) The term *RFA owner (U.S.)* means a person that owns an RFA for U.S. income tax purposes.

(32) The term *RFA owner (foreign)* means an individual or entity (including a disregarded entity) that owns an RFA for purposes of a foreign income tax.

(33) through (34) [The text of proposed §§ 1.901(m)–1(a)(33) through (34) is the same as the text of §§ 1.901(m)–1T(a)(33) through (34) published elsewhere in this issue of the **Federal Register**.]

(35) The term *section 901(m) payor* means a person eligible to claim the foreign tax credit allowed under section 901(a), regardless of whether the person chooses to claim the foreign tax credit, as well as a section 902 corporation (as defined in section 909(d)(5)). If members of a U.S. affiliated group of corporations (as defined in section 1504) file a consolidated return, each member is a separate section 901(m) payor. If individuals file a joint return, those individuals are treated as a single section 901(m) payor.

(36) through (38) [The text of proposed §§ 1.901(m)–1(a)(36) through (38) is the same as the text of §§ 1.901(m)–1T(a)(36) through (38) published elsewhere in this issue of the **Federal Register**.]

(39) The term *tentative disqualified tax amount* has the meaning provided in § 1.901(m)–3(b)(2).

(40) through (41) [The text of proposed §§ 1.901(m)–1(a)(40) through (41) is the same as the text of §§ 1.901(m)–1T(a)(40) through (41) published elsewhere in this issue of the **Federal Register**.]

(42) The term *U.S. basis deduction* has the meaning provided in § 1.901(m)–5(b)(3).

(43) through (45) [The text of proposed §§ 1.901(m)–1(a)(43) through (45) is the same as the text of §§ 1.901(m)–1T(a)(43) through (45) published elsewhere in this issue of the **Federal Register**.]

(b) *Effective/applicability date.* (1) Paragraphs (a)(1), (2), (3), (4), (5), (9), (12), (15), (16), (17), (22), (23), (24), (25), (29), (30), (31), (32), (35), (39), and (42) of this section apply to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(2) [The text of proposed § 1.901(m)–1(b)(2) is the same as the text of § 1.901(m)–1T(b)(2) published elsewhere in this issue of the **Federal Register**.]

(3) Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section, § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), and §§ 1.901(m)–3 through 1.901(m)–8 (excluding § 1.901(m)–4(e)) to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 4.** Section 1.901(m)–2 is added to read as follows:

§ 1.901(m)–2 Covered asset acquisitions and relevant foreign assets.

(a) through (b)(3) [The text of proposed §§ 1.901(m)–2(a) through (b)(3) is the same as the text of §§ 1.901(m)–2T(a) through (b)(3) published elsewhere in this issue of the **Federal Register**.]

(4) Any transaction (or series of transactions occurring pursuant to a plan) to the extent it is treated as an acquisition of assets for purposes of U.S. income tax and as the acquisition of an interest in a fiscally transparent entity for purposes of a foreign income tax;

(5) Any transaction (or series of transactions occurring pursuant to a plan) to the extent it is treated as a partnership distribution of one or more assets the U.S. basis of which is determined by section 732(b) or 732(d) or which causes the U.S. basis of the partnership's remaining assets to be adjusted under section 734(b), provided the transaction results in an increase in the U.S. basis of one or more of the assets distributed by the partnership or retained by the partnership without a corresponding increase in the foreign basis of such assets; and

(6) Any transaction (or series of transactions occurring pursuant to a plan) to the extent it is treated as an acquisition of assets for purposes of both U.S. income tax and a foreign income tax, provided the transaction results in an increase in the U.S. basis without a corresponding increase in the foreign basis of one or more assets.

(c) *Relevant foreign asset*—(1) [The text of proposed § 1.901(m)–2(c)(1) is the same as the text of § 1.901(m)–

2T(c)(1) published elsewhere in this issue of the **Federal Register**.]

(2) *RFA status with respect to a foreign income tax.* An asset is relevant in determining foreign income if income, deduction, gain, or loss attributable to the asset is taken into account in determining foreign income immediately after the CAA, or would be taken into account in determining foreign income immediately after the CAA if the asset were to give rise to income, deduction, gain, or loss at such time.

(3) *Subsequent RFA status with respect to another foreign income tax.* After a CAA, an asset will become an RFA with respect to another foreign income tax if, pursuant to a plan or series of related transactions that have a principal purpose of avoiding the application of section 901(m), an asset that was not relevant in determining foreign income for purposes of that foreign income tax immediately after the CAA becomes relevant in determining such foreign income. A principal purpose of avoiding section 901(m) will be deemed to exist if income, deduction, gain, or loss attributable to the asset is taken into account in determining such foreign income within the one-year period following the CAA, or would be taken into account in determining such foreign income during such time if the asset were to give rise to income, deduction, gain, or loss within the one-year period.

(d) [The text of proposed § 1.901(m)–2(d) is the same as the text of § 1.901(m)–2T(d) published elsewhere in this issue of the **Federal Register**.]

(e) *Examples.* The following examples illustrate the rules of this section:

Example 1. CAA involving an acquisition of a partnership interest for foreign income tax purposes—(i) *Facts.* (A) FPS is an entity organized in Country F that is treated as a partnership for both U.S. and Country F income tax purposes. FPS is owned 50/50 by FC1 and FC2, each of which is a corporation organized in Country F and treated as a corporation for both U.S. and Country F income tax purposes. FPS has a single asset, Asset A. USP, a domestic corporation, owns all the interests in DE, a disregarded entity.

(B) Pursuant to the same transaction, USP acquires FC1's interest in FPS, and DE acquires FC2's interest in FPS. For U.S. income tax purposes, with respect to USP, the acquisition of the interests in FPS is treated as the acquisition of Asset A by USP. *See* Rev. Rul. 99–6, 1999–1 C.B. 432. For Country F tax purposes, the acquisitions of the interests of FPS by USP and DE are treated as acquisitions of partnership interests.

(ii) *Result.* The transaction is a CAA under paragraph (b)(4) of this section because it is treated as the acquisition of Asset A for U.S. income tax purposes and the acquisition of interests in a partnership for Country F tax purposes.

Example 2. CAA involving an asset acquisition for purposes of both U.S. income tax and a foreign income tax—(i) *Facts.* (A) USP, a domestic corporation, wholly owns CFC1, a foreign corporation, and CFC1 wholly owns CFC2, also a foreign corporation. CFC1 and CFC2 are organized in Country F. CFC1 owns Asset A.

(B) In an exchange described in section 351, CFC1 transfers Asset A to CFC2 in exchange for CFC2 common stock and cash. CFC1 recognizes gain on the exchange under section 351(b). Under section 362(a), CFC2's U.S. basis in Asset A is increased by the gain recognized by CFC1. For Country F tax purposes, gain or loss is not recognized on the transfer of Asset A to CFC2, and therefore there is no increase in the foreign basis in Asset A.

(ii) *Result.* The transaction is a CAA under paragraph (b)(6) of this section because it is treated as an acquisition of Asset A by CFC2 for both U.S. and Country F income tax purposes, and it results in an increase in the U.S. Basis of Asset A without a corresponding increase in the foreign basis of Asset A.

Example 3. RFA status determined immediately after CAA; application of principal purpose rule—(i) *Facts.* (A) USP1 and USP2 are unrelated domestic corporations. USP1 wholly owns USSub, also a domestic corporation. On January 1 of Year 1, USP2 acquires all of the stock of USSub from USP1 in a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies. Immediately after the acquisition, none of the income, deduction, gain, or loss attributable to any of the assets of USSub is taken into account in determining foreign income for purposes of a foreign income tax nor would such items be taken into account in determining foreign income for purposes of a foreign income tax immediately after the acquisition if such assets were to give rise to income, deduction, gain, or loss immediately after the acquisition.

(B) On December 1 of Year 1, USSub contributes all its assets to FSub, its wholly owned subsidiary, which is a corporation for both U.S. and Country X income tax purposes, in a transfer described in section 351 (subsequent transfer). USSub recognizes no gain or loss for U.S. or Country X income tax purposes as a result of the subsequent transfer. As a result of the subsequent transfer, income, deduction, gain, or loss attributable to the assets of USSub that were transferred to FSub is taken into account in determining foreign income of FSub for Country X tax purposes.

(ii) *Result.* (A) Under paragraph (b)(1) of this section, the acquisition by USP2 of the stock of USSub is a section 338 CAA. Under paragraph (c)(1) of this section, none of the assets of USSub are RFAs immediately after the CAA, because none of the income, deduction, gain, or loss attributable to such assets is taken into account for purposes of determining foreign income with respect to any foreign income tax immediately after the CAA (nor would such items be taken into account for purposes of determining foreign income immediately after the CAA if such assets were to give rise to income, deduction, gain, or loss at such time).

(B) Although the subsequent transfer is not a CAA under paragraph (b) of this section, the subsequent transfer causes the assets of USSub to become relevant in the hands of FSub in determining foreign income for Country X tax purposes. Because the subsequent transfer occurred within the one-year period following the CAA, it is presumed to have a principal purpose of avoiding section 901(m). Accordingly, under paragraph (c)(2) of this section, the assets of USSub with respect to the CAA occurring on January 1 of Year 1 become RFAs with respect to Country X tax as a result of the subsequent transfer. Thus, a basis difference with respect to Country X tax must be computed for the RFAs and taken into account under section 901(m).

(f) *Effective/applicability date.* (1) [The text of proposed § 1.901(m)–2(f)(1) is the same as the text of § 1.901(m)–2T(f)(1) published elsewhere in this issue of the **Federal Register**.]

(2) Paragraphs (b)(4) through (b)(6), (c)(2), (c)(3), and (e) of this section apply to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(3) Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section (excluding paragraph (d) of this section) to all CAAs occurring on or after December 7, 2016 and consistently apply § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, and §§ 1.901(m)–3 through 1.901(m)–8 (excluding § 1.901(m)–4(e)) to all CAAs occurring on or after January 1, 2011. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 5.** Section 1.901(m)–3 is added to read as follows:

§ 1.901(m)–3 Disqualified tax amount and aggregate basis difference carryover.

(a) *In general.* If a section 901(m) payor has an aggregate basis difference, with respect to a foreign income tax and a foreign payor, for a U.S. taxable year, the section 901(m) payor must determine the portion of a foreign income tax amount that is disqualified under section 901(m) (disqualified tax amount). Paragraph (b) of this section provides rules for determining the disqualified tax amount. Paragraph (c) of this section provides rules for determining what portion, if any, of aggregate basis difference will be carried forward to the next U.S. taxable year (aggregated basis difference carryover). Paragraph (d) of this section provides the effective/applicability date.

(b) *Disqualified tax amount*—(1) *In general.* A section 901(m) payor's disqualified tax amount is not taken into account in determining the credit allowed under section 901(a). If the section 901(m) payor is a section 902 corporation, the disqualified tax amount is not taken into account for purposes of section 902 or 960. Sections 78 and 275 do not apply to the disqualified tax amount. The disqualified tax amount is allowed as a deduction to the extent otherwise deductible (see sections 164, 212, and 964 and the regulations under those sections).

(2) *Determination of disqualified tax amount*—(i) *In general.* Except as provided in paragraph (b)(2)(iv) of this section, the disqualified tax amount is equal to the lesser of the foreign income tax amount that is paid or accrued by, or considered paid or accrued by, the section 901(m) payor for the U.S. taxable year or the tentative disqualified tax amount. All calculations are determined with respect to each separate category described in § 1.904–4(m).

(ii) *Tentative disqualified tax amount.* The tentative disqualified tax amount is equal to the amount determined under paragraph (b)(2)(ii)(A) of this section reduced (but not below zero) by the amount described in paragraph (b)(2)(ii)(B) of this section.

(A) The product of—

(*1*) The sum of the foreign income tax amount and the FCCTs that are paid or accrued by, or considered paid or accrued by, the section 901(m) payor, and

(*2*) A fraction, the numerator of which is the aggregate basis difference, but not in excess of the allocable foreign income, and the denominator of which is the allocable foreign income.

(B) The amount of the FCCT that is a disqualified tax amount of the section 901(m) payor with respect to another foreign income tax.

(iii) *Allocable foreign income*—(A) *No allocation required.* Except as provided in paragraph (b)(2)(iii)(D) of this section, if the entire foreign income tax amount is paid or accrued by, or considered paid or accrued by, a single section 901(m) payor, then the allocable foreign income is equal to the entire foreign income, determined with respect to each separate category described in § 1.904–4(m).

(B) *Allocation required.* Except as provided in paragraph (b)(2)(iii)(D) of this section, if the foreign income tax amount is allocated to, and considered paid or accrued by, more than one person, a section 901(m) payor's allocable foreign income is equal to the portion of the foreign income that relates to the foreign income tax amount allocated to that section 901(m) payor, determined with respect to each separate category described in § 1.904–4(m).

(C) *Rules for allocations.* This paragraph (b)(2)(iii)(C) provides allocation rules that apply to determine allocable foreign income in certain cases.

(*1*) If the foreign payor is involved in a mid-year transaction and the foreign income tax amount is allocated under § 1.336–2(g)(3)(ii), 1.338–9(d), or 1.901–2(f)(4), then, to the extent any portion of the foreign income tax amount is allocated to, and considered paid or accrued by, a section 901(m) payor, the allocable foreign income of the section 901(m) payor is determined in accordance with the principles of § 1.1502–76(b). To the extent the foreign income tax amount is allocated to an entity that is a partnership for U.S. income tax purposes, a portion of the foreign income is first allocated to the partnership in accordance with the principles of § 1.1502–76(b), which is then allocated under the rules of paragraph (b)(2)(iii)(C)(*2*) of this section to determine the allocable foreign income of a section 901(m) payor that owns an interest in the partnership directly or indirectly through one or more other partnerships for U.S. income tax purposes.

(*2*) If the foreign income tax amount is considered paid or accrued by a section 901(m) payor for a U.S. taxable year under § 1.702–1(a)(6), the determination of the allocable foreign income must be consistent with the allocation of the foreign income tax amount that relates to the foreign income. *See* § 1.704–1(b)(4)(viii).

(*3*) If the foreign income tax amount that is allocated to, and considered paid or accrued by, a section 901(m) payor for a U.S. taxable year is determined under § 1.901–2(f)(3)(i), the allocable foreign income is determined in accordance with § 1.901–2(f)(3)(iii).

(D) *Failure to substantiate allocable foreign income.* If, pursuant to section 901(m)(3)(A), a section 901(m) payor fails to substantiate its allocable foreign income to the satisfaction of the Secretary, then allocable foreign income will equal the amount determined by dividing the sum of the foreign income tax amount and the FCCTs that are paid or accrued by, or considered paid or accrued by, the section 901(m) payor, by the highest marginal tax rate applicable to income of the foreign payor under foreign tax law.

(iv) *Special rule.* A section 901(m) payor's disqualified tax amount is zero for a U.S. taxable year if:

(A) The section 901(m) payor's aggregate basis difference for the U.S. taxable year is a negative amount;

(B) Foreign income is less than or equal to zero for the foreign taxable year of the foreign payor; or

(C) The foreign income tax amount that is paid or accrued by, or considered paid or accrued by, the section 901(m) payor for the U.S. taxable year is zero.

(3) *Examples.* The following examples illustrate the rules of paragraph (b)(2) of this section. For purposes of all the examples, unless otherwise specified: USP is a domestic corporation. CFC1, CFC2, DE1, and DE2 are organized in Country F and are treated as corporations for Country F tax purposes. CFC1 and CFC2 are section 902 corporations (as defined in section 909(d)(5)). DE1 and DE2 are disregarded entities. USP, CFC1, and CFC2 have a calendar year for both U.S. and Country F income tax purposes, and DE1 and DE2 have a calendar year for Country F tax purposes. Country F and Country G each impose a single tax that is a foreign income tax . CFC1, CFC2, DE1, and DE2 each have a functional currency of the u with respect to all activities. At all relevant times, 1u equals $1. All amounts are stated in millions. The examples assume that the applicable cost recovery method for property results in basis being recovered ratably over the life of the property beginning on the first day of the U.S. taxable year in which the property is acquired or placed into service; there is a single § 1.904–4(m) separate category with respect to a foreign income and foreign income tax amount; and a section 901(m) payor properly substantiates its allocable foreign income to the satisfaction of the Secretary.

Example 1. Determining aggregate basis difference; multiple foreign payors—(i) *Facts.* CFC1 wholly owns CFC2 and DE1. DE1 wholly owns DE2. Assume that the tax laws of Country F do not allow combined income reporting or the filing of consolidated income tax returns. Accordingly, CFC1, CFC2, DE1, and DE2 file separate tax returns for Country F tax purposes. USP acquires all of the stock of CFC1 in a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies for both CFC1 and CFC2.

(ii) *Result.* (A) The acquisition of CFC1 gives rise to four separate CAAs under § 1.901(m)–2(b). The acquisition of the stock of CFC1 and the deemed acquisition of the stock of CFC2 under section 338(h)(3)(B) is each a Section 338 CAA under § 1.901(m)–2(b)(1). Furthermore, because the deemed acquisition of the assets of DE1 and DE2 for U.S. income tax purposes is disregarded for Country F tax purposes, each acquisition is a CAA under § 1.901(m)–2(b)(2). Because these four CAAs occur pursuant to a plan, under § 1.901(m)–1(a)(3) they are part of an aggregated CAA transaction. Under

§ 1.901(m)–1(a)(31), CFC1 is the RFA owner (U.S.) with respect to its assets and those of DE1 and DE2. CFC2 is the RFA owner (U.S.) with respect to its assets. Under § 1.901(m)–1(a)(23), CFC1, CFC2, DE1, and DE2 are each a foreign payor for Country F tax purposes. Under § 1.901(m)–1(a)(35), CFC1 is the section 901(m) payor with respect to foreign income tax amounts for which CFC1, DE1, and DE2 are the foreign payors (see §§ 1.901–2(f)(1) and 1.901–2(f)(4)(ii)). CFC2 is the section 901(m) payor with respect to foreign income tax amounts for which CFC2 is the foreign payor (see § 1.901–2(f)(1)).

(B) In determining aggregate basis difference under § 1.901(m)–1(a)(1) for a U.S. taxable year of CFC1, CFC1 has three computations with respect to Country F tax, because there are three foreign payors for Country F tax purposes whose foreign income tax amount, if any, is considered paid or accrued by CFC1 as the section 901(m) payor. Furthermore, for each U.S. taxable year, CFC1 will compute a separate disqualified tax amount and aggregate basis difference Carryover (if any) under paragraph (b)(2) of this section, with respect to each foreign payor.

(C) In determining aggregate basis difference for a U.S. taxable year of CFC2 under § 1.901(m)–1(a)(1), CFC2 has a single computation with respect to Country F tax, because there is a single foreign payor (CFC2) for Country F tax purposes whose foreign income tax amount, if any, is considered paid or accrued by CFC2 as the section 901(m) payor. Furthermore, for each U.S. taxable year, CFC2 will compute a disqualified tax amount and aggregate basis difference Carryover (if any) under paragraph (b)(2) of this section.

(iii) *Alternative facts.* Assume the same facts as in paragraph (i) of this *Example 1,* except that foreign income for Country F tax purposes is based on combined income (within the meaning of § 1.901–2(f)(3)(ii)) of CFC1, CFC2, DE1, and DE2. For purposes of determining an aggregate basis difference for a U.S. taxable year of CFC1 under § 1.901(m)–1(a)(1), CFC1, DE1, and DE2 are treated as a single foreign payor because all of the items of income, deduction, gain, or loss with respect to CFC1, DE1, and DE2 are included in the earnings and profits of CFC1 for U.S. income tax purposes. For each U.S. taxable year, CFC1 will therefore compute a single aggregate basis difference, disqualified tax amount, and aggregate basis difference carryover. The result for CFC2 under the alternative facts is the same as in paragraph (ii)(C) of this *Example 1.*

Example 2. Computation of disqualified tax amount—(i) *Facts.* On December 31 of Year 0, USP acquires all of the stock of CFC1 in a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies (Acquisition). CFC1 owns four assets (Asset A, Asset B, Asset C, and Asset D, and collectively, Assets) and conducts activities in Country F and in a Country G branch. The activities conducted by CFC1 in Country G are not subject to tax in Country F. The tax rate is 25% in Country F and 30% in Country G. For Country F tax purposes, CFC1's foreign income and foreign income tax amount for each foreign taxable year 1 through 15 is 100u and $25 (25u translated at the exchange rate of $1 = 1u), respectively. For Country G tax purposes, CFC1's foreign income and foreign income tax amount for each foreign taxable year 1 through 5 is 400u and $120 (120u translated at the exchange rate of $1 = 1u), respectively. No dispositions occur for any of the Assets during the applicable cost recovery period. Additional facts relevant to each of the Assets are summarized below.

Assets	Relevant foreign income tax	Basis difference	Applicable cost recovery period (years)	Cost recovery amount
Asset A	Country F tax	150u	15	10u (150u/15).
Asset B	Country F tax	50u	5	10u (50u/5).
Asset C	Country G tax	300u	5	60u (300u/5).
Asset D	Country G tax	(100u)	5	negative 20u (negative 100/5).

(ii) *Result.* (A) Under § 1.901(m)–2(b)(1), the Acquisition of the stock of CFC1 is a Section 338 CAA. Under § 1.901(m)–2(c)(1), Assets A and B are RFAs with respect to Country F tax, because they are relevant in determining foreign income of CFC1 for Country F tax purposes and were owned by CFC1 when the Acquisition occurred. Assets C and D are RFAs with respect to Country G tax, because they are relevant in determining foreign income of CFC1 for Country G tax purposes and were owned by CFC1 when the Acquisition occurred. Under § 1.901(m)–1(a)(31), CFC1 is the RFA owner (U.S.) with respect to all of the RFAs. Under § 1.901(m)–1(a)(35) and (a)(23), CFC1 is the section 901(m) payor and the foreign payor for Country F and Country G tax purposes.

(B) In determining aggregate basis difference for a U.S. taxable year of CFC1, CFC1 has two computations, one with respect to Country F tax and one with respect to Country G tax. Under § 1.901(m)–1(a)(1), the aggregate basis difference for a U.S. taxable year with respect to Country F tax is equal to the sum of the allocated basis differences with respect to Assets A and B for the U.S. taxable year. Under § 1.901(m)–1(a)(5), allocated basis differences are comprised of cost recovery amounts and disposition amounts. Because there are no dispositions, the only allocated basis differences taken into account in determining an aggregate basis difference are cost recovery amounts. Under § 1.901(m)–5(b), any cost recovery amounts are attributed to CFC1, because CFC1 is the section 901(m) payor and RFA owner (U.S.) with respect to all of the Assets. For each U.S. taxable year, CFC1 will compute a separate disqualified tax amount and aggregate basis difference carryover (if any) with respect to Country F tax and Country G tax under paragraph (b)(2) of this section. For purposes of both disqualified tax amount computations, because CFC1 is the section 901(m) payor and foreign payor, the foreign income tax amount paid or accrued by CFC1 with respect to Country F tax and Country G tax, respectively, will be the entire foreign income tax amount and CFC1's allocable foreign income will be the entire foreign income.

(C) With respect to Country F tax, in U.S. taxable years 1 through 5, CFC1 has an aggregate basis difference of 20u each year (10u cost recovery amount with respect to Asset A plus 10u cost recovery amount with respect to Asset B). For U.S. taxable years 1 through 5, under paragraph (b)(2) of this section, the disqualified tax amount each year is $5, the lesser of two amounts: the tentative disqualified tax amount, in this case, $5 ($25 foreign income tax amount × (20u aggregate basis difference/100u allocable foreign income)), or the foreign income tax amount paid or accrued by CFC1, in this case, $25. After U.S. taxable year 5, Asset B has no unallocated basis difference with respect to Country F tax. Accordingly, in U.S. taxable years 6 through 15, CFC1 has an aggregate basis difference of 10u each year. Accordingly, for U.S. taxable years 6 through 15, the disqualified tax amount each year is $2.50, the lesser of two amounts: the tentative disqualified tax amount, in this case, $2.50 ($25 foreign income tax amount × (10u aggregate basis difference/100u allocable foreign income)), or the foreign income tax amount paid or accrued by CFC1, in this case, $25. After U.S. taxable year 15, Asset A has no unallocated basis difference with respect to Country F tax and, therefore, CFC1 has no disqualified tax amount with respect to Country F Tax.

(D) With respect to Country G tax, in U.S. taxable years 1 through 5, CFC1 has an aggregate basis difference of 40u each year (60u cost recovery amount with respect to Asset C + (20u) cost recovery amount with respect to Asset D). For U.S. taxable years 1 through 5, under paragraph (b)(2) of this section, the disqualified tax amount each year is $12, the lesser of two amounts: the tentative disqualified tax amount, in this case, $12 ($120 foreign income tax amount × (40u aggregate basis difference/400u allocable foreign income)), or the foreign income tax amount paid or accrued by CFC1, in this case, $120. After U.S. taxable year 5, Asset C and Asset D have no unallocated basis difference with respect to Country G

tax. Accordingly, in U.S. taxable years 6 through 15, CFC1 has no disqualified tax amount with respect to Country G Tax.

Example 3. FCCT—(i) *Facts.* In U.S. taxable year 1, USP acquires all of the interests in DE1 in a transaction (Transaction) that is treated as a stock acquisition for Country F tax purposes. Immediately after the Transaction, DE1 owns assets (Pre-Transaction Assets), all of which are used in a Country G branch and give rise to income that is taken into account for Country F tax and Country G tax purposes. After the Transaction, DE1 acquires additional assets (Post-Transaction Assets), which are not used by the Country G branch. Both Country F and Country G have a tax rate of 30%. Country F imposes worldwide tax on its residents and provides a foreign tax credit for taxes paid to other jurisdictions. In foreign taxable year 3, 100u of income is attributable to DE1's Post-Transaction Assets and 100u of income is attributable to DE1's Pre-Transaction Assets. For Country G tax purposes, the foreign income is 100u and foreign income tax amount is 30u (30% × 100u). For Country F tax purposes, the foreign income is 200u and the pre-foreign tax credit tax is 60u (30% × 200u). The 60u of Country F pre-foreign tax credit tax is reduced by the 30u foreign income tax amount imposed for Country G tax purposes. Thus, the foreign income tax amount for Country F tax purposes is $30 (30u translated into dollars at the exchange rate of $1 = 1u). Assume that for U.S. taxable year 3 USP has 100u aggregate basis difference with respect to Country F tax and 100u aggregate basis difference with respect to Country G tax. USP does not dispose of DE1 or any assets of DE1 in U.S. taxable year 3.

(ii) *Result.* (A) Under § 1.901(m)–2(b)(2), the Transaction is a CAA. Under § 1.901(m)–2(c)(1), the Pre-Transaction Assets are RFAs with respect to both Country F tax and Country G tax, because they are relevant in determining the foreign income of DE1 for Country F tax and Country G tax purposes and were owned by DE1 when the Transaction occurred. Under § 1.901(m)–1(a)(31), USP is the RFA owner (U.S.) with respect to the RFAs. Under § 1.901(m)–1(a)(23), DE1 is a foreign payor for Country F tax and Country G tax purposes. Under § 1.901(m)–1(a)(35), USP is the section 901(m) payor with respect to foreign income tax amounts for which DE1 is the foreign payor (see § 1.901–2(f)(4)(ii)). Because the Country G foreign income tax amount is claimed as a credit for purposes of determining the Country F foreign income tax amount, the Country G foreign income tax amount is an FCCT under § 1.901(m)–1(a)(17).

(B) Under § 1.901(m)–1(a)(1), for each U.S. taxable year, USP will separately compute the aggregate basis difference with respect to Country F tax and with respect to Country G tax, and will use those amounts to separately compute a disqualified tax amount and aggregate basis difference carryover (if any) with respect to each foreign income tax . Because DE1 is a disregarded entity owned by USP during the entire U.S. taxable year 3, the foreign income tax amount paid or accrued by DE1 is not subject to allocation. Accordingly, for purposes of each of the disqualified tax amount computations, the foreign income tax amount paid or accrued by USP with respect to Country F tax and Country G tax, respectively, is the entire foreign income tax amount paid or accrued by DE1, and, under paragraph (b)(2)(iii)(A) of this section, USP's allocable foreign income will be equal to DE1's entire foreign income.

(C) As stated in paragraph (i) of this *Example 3,* for U.S. taxable year 3 USP has 100u aggregate basis difference with respect to Country F tax and 100u aggregate basis difference with respect to Country G tax. With respect to Country G tax, in U.S. taxable year 3, under paragraph (b)(2) of this section, the disqualified tax amount is $30, the lesser of the two amounts: the tentative disqualified tax amount, in this case, $30 ($30 foreign income tax amount × (100u aggregate basis difference/100u allocable foreign income)), or the foreign income tax amount considered paid or accrued by USP, in this case, $30.

(D) With respect to Country F tax, in U.S. taxable year 3, under paragraph (b)(2) of this section, the disqualified tax amount is $0, the lesser of two amounts: the tentative disqualified tax amount, in this case $0 (($30 foreign income tax amount + $30 Country G FCCT) × (100u aggregate basis difference/ 200u foreign income) = $30 reduced by $30 Country G FCCT that is a disqualified tax amount of USP), or the foreign income tax amount considered paid or accrued by USP, in this case, $30.

(c) *Aggregate basis difference carryover*—(1) *In general.* If a section 901(m) payor has an aggregate basis difference carryover for a U.S. taxable year, as determined under this paragraph (c), the aggregate basis difference carryover is taken into account in computing the section 901(m) payor's aggregate basis difference for the next U.S. taxable year. For successor rules that apply to an aggregate basis difference carryover, see § 1.901(m)–6(c).

(2) *Amount of aggregate basis difference carryover.* (i) If a section 901(m) payor's disqualified tax amount is zero, all of the section 901(m) payor's aggregate basis difference (positive or negative) for the U.S. taxable year gives rise to an aggregate basis difference carryover to the next U.S. taxable year.

(ii) If a section 901(m) payor's disqualified tax amount is not zero, then aggregate basis difference carryover can arise in either or both of the following two situations:

(A) If a section 901(m) payor's aggregate basis difference for the U.S. taxable year exceeds its allocable foreign income, the excess gives rise to an aggregate basis difference carryover.

(B) If the tentative disqualified tax amount exceeds the disqualified tax amount, the excess tentative disqualified tax amount is converted into aggregate basis difference carryover by multiplying such excess by a fraction, the numerator of which is the allocable foreign income, and the denominator of which is the sum of the foreign income tax amount and the FCCTs that are paid or accrued by, or considered paid or accrued by, the section 901(m) payor.

(3) *Example.* The following example illustrates the rule of paragraph (c) of this section.

Example. Aggregate basis difference carryover; section 901(m) payor's U.S. taxable year differs from the foreign taxable year of foreign payor—(i) *Facts.* (A) On July 1 of Year 1, CFC1 acquires all of the interests of DE1 in a transaction (Transaction) that is treated as a stock acquisition for Country F tax purposes. CFC1 and DE1 are organized in Country F and are treated as corporations for Country F tax purposes. CFC1 is a section 902 corporation (as defined in section 909(d)(5)), and DE1 is a disregarded entity . CFC1 has a calendar year for U.S. income tax purposes, and DE1 has a June 30 year-end for Country F tax purposes. Country F imposes a single tax that is a foreign income tax . CFC1 and DE1 each have a functional currency of the u with respect to all activities. Immediately after the Transaction, DE1 owns one asset, Asset A, that gives rise to income that is taken into account for Country F tax purposes. For the first U.S. taxable year (U.S. taxable year 1) there is a cost recovery amount with respect to Asset A of 9u, and for each subsequent U.S. taxable year until the U.S. basis is fully recovered, there is a cost recovery amount with respect to Asset A of 18u. There is no disposition of Asset A.

(ii) *Result.* (A) Under § 1.901(m)–2(b)(2), the Transaction is a CAA. Under § 1.901(m)–2(c)(1), Asset A is an RFA with respect to Country F tax because it is relevant in determining the foreign income of DE1 for Country F tax purposes and was owned by DE1 when the Transaction occurred. Under § 1.901(m)–1(a)(31), CFC1 is the RFA owner (U.S.) with respect to Asset A. Under § 1.901(m)–1(a)(23), DE1 is a foreign payor for Country F tax purposes. Under § 1.901(m)–1(a)(35), CFC1 is the section 901(m) payor with respect to foreign income tax amounts for which DE1 is the foreign payor (see § 1.901–2(f)(4)(ii)).

(B) Under § 1.901(m)–1(a)(1), in determining the aggregate basis difference for U.S. taxable year 1, CFC1 has one computation with respect to Country F tax. Under § 1.901(m)–1(a)(1), aggregate basis difference with respect to Country F tax is equal to the sum of allocated basis differences with respect to all RFAs, which, in this case, is only Asset A. Under § 1.901(m)–1(a)(5), allocated basis differences are comprised of cost recovery amounts and disposition amounts. Because there is no disposition of Asset A, the only allocated basis difference taken into account in determining an aggregate basis difference are cost recovery amounts with respect to Asset A. Under § 1.901(m)–5(b), any cost recovery amounts are assigned to a U.S taxable year of CFC1, because CFC1 is the section 901(m) payor and RFA owner (U.S.) with respect to Asset A. Under paragraph (b)(2) of this

section, for each U.S. taxable year, CFC1 will compute a disqualified tax amount and aggregate basis difference carryover with respect to the aggregate basis difference. Because DE1 is a disregarded entity owned by CFC1, the foreign income tax amount paid or accrued by DE1 is not subject to allocation. Accordingly, for purposes of the disqualified tax amount computation, the foreign income tax amount paid or accrued by CFC1 with respect to Country F tax is the entire foreign income tax amount paid or accrued by DE1, and under paragraph (b)(2)(iii)(A) of this section, CFC1's allocable foreign income will be equal to DE1's entire foreign income.

(C) In U.S. taxable year 1, CFC1 has an aggregate basis difference of 9u (the 9u cost recovery amount with respect to Asset A for U.S. taxable year 1). However, because the foreign taxable year of DE1, the foreign payor, will not end between July 1 and December 31, there will not be a foreign income tax amount for U.S. taxable year 1. Because the foreign income tax amount considered paid or accrued by CFC1 for U.S. taxable year 1 is zero, under paragraph (b)(2)(iv) of this section, the disqualified tax amount for U.S. taxable year 1 of CFC1 is also zero. Furthermore, because the disqualified tax amount is zero, under paragraph (c)(2)(i) of this section, CFC1 has an aggregate basis difference carryover equal to 9u, the entire amount of the aggregate basis difference for U.S. taxable year 1. Under paragraph (c)(1) of this section, the 9u aggregate basis difference carryover is taken into account in computing CFC1's aggregate basis difference for U.S. taxable year 2. Accordingly, in U.S. taxable year 2, CFC1 has an aggregate basis difference of 27u (18u cost recovery amount for U.S. taxable year 2, plus 9u aggregate basis difference carryover from U.S. taxable year 1).

(d) *Effective/applicability date.* This section applies to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section, § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, and §§ 1.901(m)–4 through 1.901(m)–8 (excluding § 1.901(m)–4(e)) to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 6.** Section 1.901(m)–4 is added to read as follows:

§ 1.901(m)–4 Determination of basis difference.

(a) through (b) [The text of proposed §§ 1.901(m)–4(a) through (b) is the same as the text of §§ 1.901(m)–4T(a) through (b) published elsewhere in this issue of the **Federal Register**.]

(c) *Foreign basis election.* (1) An election (foreign basis election) may be made to apply section 901(m)(3)(C)(i)(II) by reference to the foreign basis immediately after the CAA instead of the U.S. basis immediately before the CAA. Accordingly, if a foreign basis election is made, basis difference is the U.S. basis in the RFA immediately after the CAA, less the foreign basis in the RFA immediately after the CAA. For this purpose, the foreign basis immediately after the CAA takes into account any adjustment to that foreign basis resulting from the CAA for purposes of the foreign income tax .

(2) Except as otherwise provided in this paragraph (c), a foreign basis election is made by the RFA owner (U.S.). If, however, the RFA owner (U.S.) is a partnership, each partner in the partnership (and not the partnership) may independently make a foreign basis election. In the case of one or more tiered partnerships, the foreign basis election is made at the level at which a partner is not also a partnership.

(3) The election may be made separately for each CAA, and with respect to each foreign income tax and each foreign payor. For purposes of making the foreign basis election, all CAAs that are part of an aggregated CAA transaction are treated as a single CAA. Furthermore, for purposes of making the foreign basis election, if foreign law imposes tax on the combined income (within the meaning of § 1.901–2(f)(3)(ii)) of two or more foreign payors, all foreign payors whose items of income, deduction, gain, or loss for U.S. income tax purposes are included in the U.S. taxable income or earnings and profits of a single section 901(m) payor are treated as a single foreign payor.

(4) A foreign basis election is made by using foreign basis to determine basis difference for purposes of computing a disqualified tax amount and an aggregate basis difference carryover for the U.S. taxable year, as provided under § 1.901(m)–3. A separate statement or form evidencing the foreign basis election need not be filed. Except as provided in paragraph (c)(5) and (6) of this section, in order for a foreign basis election to be effective, the election must be reflected on a timely filed original federal income tax return (including extensions) for the first U.S. taxable year that the foreign basis election is relevant to the computation of any amounts reported on such return, including on any required schedules.

(5) If the RFA owner (U.S.) is a partnership, a foreign basis election reflected on a partner's timely filed amended federal income tax return is also effective if all of the following conditions are satisfied:

(i) The partner's timely filed original federal income tax return (including extensions) for the first U.S. taxable year of the partner in which a foreign basis election is relevant to the computation of any amounts reported on such return, including on any required schedules, does not reflect the application of section 901(m);

(ii) The information provided by the partnership to the partner for purposes of applying section 901(m) and any information required to be reported by the partnership is based solely on computations that use foreign basis to determine basis difference; and

(iii) Prior to the due date of the original federal income tax return (including extensions) described in paragraph (c)(5)(i) of this section, the partner delegated the authority to the partnership to choose whether to provide the partner with information to apply section 901(m) using foreign basis, either pursuant to a written partnership agreement (within the meaning of § 1.704–1(b)(2)(ii)(*h*)) or written notice provided by the partner to the partnership.

(6) If, pursuant to paragraph (g)(3) of this section, a taxpayer chooses to have this section apply to CAAs occurring on or after January 1, 2011, a foreign basis election will be effective if the election is reflected on a timely filed amended federal income tax return (or tax returns, as applicable) filed no later than one year following the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(7) The foreign basis election is irrevocable. Relief under § 301.9100–1 is not available for the foreign basis election.

(d) *Determination of basis difference in a section 743(b) CAA*—(1) [The text of proposed § 1.901(m)–4(d)(1) is the same as the text of § 1.901(m)–4T(d)(1) published elsewhere in this issue of the **Federal Register**.]

(2) *Foreign basis election.* If a foreign basis election is made with respect to a section 743(b) CAA, then, for purposes of paragraph (d)(1) of this section, the section 743(b) adjustment is determined by reference to the foreign basis of the RFA, determined immediately after the CAA.

(e) [The text of proposed § 1.901(m)–4(e) is the same as the text of § 1.901(m)–4T(e) published elsewhere in this issue of the **Federal Register**.]

(f) *Examples.* The following examples illustrate the rules of this section:

Example 1. Scope of basis choice; identifying separate CAAs, RFA owners (U.S.), and foreign payors in an aggregated CAA transaction —(i) *Facts.* CFC1 wholly owns CFC2, both of which are section 902 corporations (as defined in section 909(d)(5)), organized in Country F, and treated as corporations for Country F tax purposes. CFC1 also wholly owns DE1, and DE1 wholly owns DE2. DE1 and DE2 are entities organized in Country F treated as corporations for Country F tax purposes and as disregarded entities for U.S. income tax purposes. Country F imposes a single tax that is a foreign income tax . All of the stock of CFC1 is acquired in a qualified stock purchase (within the meaning of section 338(d)(3)) to which section 338(a) applies for both CFC1 and CFC2. For Country F tax purposes, the transaction is treated as an acquisition of the stock of CFC1.

(ii) *Result.* (A) The acquisition of CFC1 gives rise to four separate CAAs described in § 1.901(m)–2. Under § 1.901(m)–2(b)(1), the acquisition of the stock of CFC1 and the deemed acquisition of the stock of CFC2 under section 338(h)(3)(B) are each a section 338 CAA. Furthermore, because the deemed acquisition of the assets of each of DE1 and DE2 for U.S. income tax purposes is disregarded for Country F tax purposes, the deemed acquisitions are CAAs under § 1.901(m)–2(b)(2). Because the four CAAs occurred pursuant to a plan, under § 1.901(m)–1(a)(3), all of the CAAs are part of an aggregated CAA transaction. Under § 1.901(m)–1(a)(31), CFC1 is the RFA owner (U.S.) with respect to its assets and the assets of DE1 and DE2 that are RFAs. CFC2 is the RFA owner (U.S.) with respect to its assets that are RFAs. Under § 1.901(m)–1(a)(23), CFC1, CFC2, DE1, and DE2 are each a foreign payor for Country F tax purposes.

(B) Under paragraph (c) of this section, a foreign basis election may be made by the RFA owner (U.S.). The election is made separately with respect to each CAA (for this purpose, treating all CAAs that are part of an aggregated CAA transaction as a single CAA) and with respect to each foreign income tax and foreign payor. Thus, in this case, CFC1 can make a separate foreign basis election for one or more of the following three groups of RFAs: RFAs that are relevant in determining foreign income of CFC1; RFAs that are relevant in determining foreign income of DE1; and RFAs that are relevant in determining foreign income of DE2. Furthermore, CFC2 can make a foreign basis election for all of its RFAs that are relevant in determining its foreign income.

Example 2. Scope of basis choice; RFA owner (U.S.) is a partnership—(i) *Facts.* USPS is a domestic partnership for which a section 754 election is in effect. USPS owns two assets, the stock of DE1 and DE2. DE1 is an entity organized in Country X and treated as a corporation for Country X tax purposes. DE2 is an entity organized in Country Y and treated as a corporation for Country Y tax purposes. DE1 and DE2 are disregarded entities. Country X and Country Y each impose a single tax that is a foreign income tax . US1 and US2, unrelated domestic corporations, and FP, a foreign person unrelated to US1 and US2, acquire partnership interests in USPS from existing partners of USPS pursuant to the same plan.

(ii) *Result.* Under § 1.901(m)–2(b)(3), the acquisitions of the partnership interests in USPS by US1, US2, and FP each give rise to separate section 743(b) CAAs, but under § 1.901(m)–1(a)(3), they are treated as an aggregated CAA transaction because they occur as part of a plan. Under § 1.901(m)–1(a)(31), USPS is the RFA owner (U.S.) with respect to the assets of DE1 and DE2 that are RFAs. Under § 1.901(m)–1(a)(23), DE1 is a foreign payor for Country X tax purposes and DE2 is a foreign payor for Country Y tax purposes. Because the RFA owner (U.S.) is a partnership, paragraph (c)(2) of this section provides that US1, US2, and FP (the relevant partners in USPS) separately choose whether to make a foreign basis election for purposes of determining basis difference. Furthermore, under paragraph (c)(3) of this section, the choice to make the election is made separately by each partner with respect to each foreign payor. Thus, in this case, each partner may make separate elections for the RFAs that are relevant in determining foreign income of DE1 for Country X tax purposes and the RFAs that are relevant in determining foreign income of DE2 for Country Y tax purposes.

(g) *Effective/applicability date*—(1) [The text of proposed § 1.901(m)–4(g)(1) is the same as the text of § 1.901(m)–4T(g)(1) published elsewhere in this issue of the **Federal Register**.]

(2) Except for paragraphs (a), (b), (d)(1), and (e) of this section, this section applies to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(3) Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section (excluding paragraph (e) of this section), § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, § 1.901(m)–3, and §§ 1.901(m)–5 through 1.901(m)–8 to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 7.** Section 1.901(m)–5 is added to read as follows:

§ 1.901(m)–5 Basis difference taken into account.

(a) *In general.* This section provides rules for determining the amount of basis difference with respect to an RFA that is taken into account in a U.S. taxable year for purposes of determining the disqualified portion of a foreign income tax amount. Paragraph (b) of this section provides rules for determining a cost recovery amount and assigning that amount to a U.S. taxable year of a single section 901(m) payor when the RFA owner (U.S.) is the section 901(m) payor. Paragraph (c) of this section provides rules for determining a disposition amount and assigning that amount to a U.S. taxable year of a single section 901(m) payor when the RFA owner (U.S.) is the section 901(m) payor. Paragraph (d) of this section provides rules for allocating cost recovery amounts and disposition amounts when the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes. Paragraph (e) of this section provides special rules for allocating cost recovery amounts and disposition amounts with respect to certain section 743(b) CAAs. Paragraph (f) of this section provides special rules for allocating certain disposition amounts when a foreign payor is transferred in a mid-year transaction. Paragraph (g) of this section provides special rules for allocating both cost recovery amounts and disposition amounts in certain cases in which the RFA owner (U.S.) either is a reverse hybrid or a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid. Paragraph (h) of this section provides examples illustrating the application of this section. Paragraph (i) of this section provides the effective/applicability date.

(b) *Basis difference taken into account under applicable cost recovery method*—(1) *In general.* When the RFA owner (U.S.) is a section 901(m) payor, all of a cost recovery amount is attributed to the section 901(m) payor and assigned to the U.S. taxable year of the section 901(m) payor in which the corresponding U.S. basis deduction is taken into account under the applicable cost recovery method. This is the case regardless of whether the deduction is deferred or disallowed for U.S. income tax purposes. If instead the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes, a cost recovery amount is allocated to one or more section 901(m) payors under paragraph (d) of this section, except as provided in paragraphs (e) and (g) of this section. If a cost recovery amount arises from an RFA with respect to a section 743(b) CAA, in certain cases the cost recovery amount is allocated to a section 901(m) payor under paragraph (e) of this section. In certain cases in which the RFA owner (U.S.) either is a reverse hybrid or a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid, a cost recovery amount is allocated to one

or more section 901(m) payors under paragraph (g) of this section.

(2) *Determining a cost recovery amount*—(i) [The text of proposed § 1.901(m)–5(b)(2)(i) is the same as the text of § 1.901(m)–5T(b)(2)(i) published elsewhere in this issue of the **Federal Register**.]

(ii) *U.S. basis subject to multiple cost recovery methods.* If the entire U.S. basis is not subject to the same cost recovery method, the applicable cost recovery method for determining the cost recovery amount is the cost recovery method that applies to the portion of the U.S. basis that corresponds to the basis difference.

(3) *Applicable cost recovery method.* For purposes of section 901(m), an applicable cost recovery method includes any method for recovering the cost of property over time for U.S. income tax purposes (each application of a method giving rise to a ''U.S. basis deduction''). Such methods include depreciation, amortization, or depletion, as well as a method that allows the cost (or a portion of the cost) of property to be expensed in the year of acquisition or in the placed-in-service year, such as under section 179. Applicable cost recovery methods do not include any provision allowing the U.S. basis to be recovered upon a disposition of an RFA.

(c) *Basis difference taken into account as a result of a disposition*—(1) *In general.* Except as provided in paragraph (f) of this section, when the RFA owner (U.S.) is a section 901(m) payor, all of a disposition amount is attributed to the section 901(m) payor and assigned to the U.S. taxable year of the section 901(m) payor in which the disposition occurs. If instead the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes, except as provided in paragraphs (e), (f), and (g) of this section, a disposition amount is allocated to one or more section 901(m) payors under paragraph (d) of this section. If a disposition amount arises from an RFA with respect to a section 743(b) CAA, in certain cases the disposition amount is allocated to a section 901(m) payor under paragraph (e) of this section. If there is a disposition of an RFA in a foreign taxable year of a foreign payor during which there is a mid-year transaction, in certain cases a disposition amount is allocated under paragraph (f) of this section. In certain cases in which the RFA owner (U.S.) either is a reverse hybrid or a fiscally transparent entity for both U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid, a disposition amount is allocated to one or more section 901(m) payors under paragraph (g) of this section.

(2) [The text of proposed § 1.901(m)–5(c)(2) is the same as the text of § 1.901(m)–5T(c)(2) published elsewhere in this issue of the **Federal Register**.]

(d) *General rules for allocating and assigning a cost recovery amount or a disposition amount when the RFA owner (U.S.) is a fiscally transparent entity*—(1) *In general.* Except as provided in paragraphs (e), (f), and (g) of this section, this paragraph (d) provides rules for allocating a cost recovery amount or a disposition amount when the RFA owner (U.S.) is a fiscally transparent entity for U.S. income tax purposes in which a section 901(m) payor directly or indirectly owns an interest, as well as for assigning the allocated amount to a U.S. taxable year of the section 901(m) payor. For purposes of this paragraph (d), unless otherwise indicated, a reference to direct or indirect ownership in an entity means for U.S. income tax purposes. For purposes of this paragraph (d), a person indirectly owns an interest in an entity for U.S. income tax purposes if the person owns the interest through one or more fiscally transparent entities for U.S. income tax purposes, and at least one of the fiscally transparent entities is not a disregarded entity . For purposes of this paragraph (d), a person indirectly owns an interest in an entity for foreign income tax purposes if the person owns the interest through one or more fiscally transparent entities for foreign income tax purposes. If the RFA owner (U.S.) is a lower-tier fiscally transparent entity for U.S. income tax purposes in which the section 901(m) payor indirectly owns an interest, the rules of this section apply in a manner consistent with the application of these rules when the section 901(m) payor directly owns an interest in the RFA owner (U.S.).

(2) *Allocation of a cost recovery amount.* A cost recovery amount is allocated to a section 901(m) payor that directly or indirectly owns an interest in the RFA owner (U.S.) to the extent the U.S. basis deduction that corresponds to the cost recovery amount is (or will be) included in the section 901(m) payor's distributive share of the income of the RFA owner (U.S.) for U.S. income tax purposes.

(3) *Allocation of a disposition amount attributable to foreign disposition gain or foreign disposition loss*—(i) *In general.* Except as provided in paragraph (f) of this section, a disposition amount attributable to foreign disposition gain or foreign disposition loss (as determined under paragraph (d)(5) of this section) is allocated under paragraph (d)(3)(ii) or (d)(3)(iii) of this section to a section 901(m) payor that directly or indirectly owns an interest in the RFA owner (U.S.).

(ii) *First allocation rule.* This paragraph (d)(3)(ii) applies when a section 901(m) payor, or a disregarded entity directly owned by a section 901(m) payor, is the foreign payor whose foreign income includes a distributive share of the foreign income of the RFA owner (foreign) and, therefore, all of the foreign income tax amount of the foreign payor is paid or accrued by, or considered paid by, the section 901(m) payor. Thus, this paragraph (d)(3)(ii) applies when the RFA owner (U.S.) is a fiscally transparent entity for both U.S. and foreign income tax purposes and a section 901(m) payor either directly owns an interest in the RFA owner (U.S.) or directly owns an interest in another fiscally transparent entity for U.S. and foreign income tax purposes, which, in turn, directly or indirectly owns an interest in the RFA owner (U.S.) for both U.S. and foreign income tax purposes. In these cases, the section 901(m) payor is allocated the portion of a disposition amount that is equal to the product of the disposition amount attributable to foreign disposition gain or foreign disposition loss, as applicable, and a fraction, the numerator of which is the portion of the foreign disposition gain or foreign disposition loss recognized by the RFA owner (foreign) for foreign income tax purposes that is (or will be) included in the foreign payor's distributive share of the foreign income of the RFA owner (foreign), and the denominator of which is the foreign disposition gain or foreign disposition loss.

(iii) *Second allocation rule.* This paragraph (d)(3)(iii) applies when neither a section 901(m) payor nor a disregarded entity directly owned by a section 901(m) payor is the foreign payor with respect to the foreign income of the RFA owner (foreign). Instead, a section 901(m) payor directly or indirectly owns an interest in the foreign payor, which is a fiscally transparent entity for U.S. income tax purposes (other than a disregarded entity directly owned by the section 901(m) payor), and, therefore, the section 901(m) payor is considered to pay or accrue only its allocated portion of the foreign income tax amount of the foreign payor. This will be the case when the foreign payor is either the RFA owner (U.S.), another fiscally transparent entity for U.S. income tax purposes (other than a disregarded entity directly owned by a section

901(m) payor) that directly or indirectly owns an interest in the RFA owner (U.S.) for both U.S. and foreign income tax purposes, or a disregarded entity directly owned by the RFA owner (U.S.). In these cases, the section 901(m) payor is allocated the portion of a disposition amount that is equal to the product of the disposition amount attributable to foreign disposition gain or foreign disposition loss, as applicable, and a fraction, the numerator of which is the portion of the foreign disposition gain or foreign disposition loss that is included in the allocable foreign income of the section 901(m) payor, and the denominator of which is the foreign disposition gain or foreign disposition loss. If allocable foreign income is not otherwise required to be determined because there is no foreign income tax amount, the numerator is the portion of the foreign disposition gain or foreign disposition loss that would be included in the allocable foreign income of the section 901(m) payor if there were a foreign income tax amount.

(4) *Allocation of a disposition amount attributable to U.S. disposition gain or U.S. disposition loss.* A section 901(m) payor that directly or indirectly owns an interest in the RFA owner (U.S.) is allocated the portion of a disposition amount that is equal to the product of the disposition amount attributable to U.S. disposition gain or U.S. disposition loss (as determined under paragraph (d)(5) of this section), as applicable, and a fraction, the numerator of which is the portion of the U.S. disposition gain or U.S. disposition loss that is (or will be) included in the section 901(m) payor's distributive share of income of the RFA owner (U.S.) for U.S. income tax purposes, and the denominator of which is the U.S. disposition gain or U.S. disposition loss.

(5) *Determining the extent to which a disposition amount is attributable to foreign or U.S. disposition gain or loss*—(i) *RFA with a positive basis difference.* When there is a disposition of an RFA with a positive basis difference and the disposition results in either a foreign disposition gain or a U.S. disposition loss, but not both, the entire disposition amount is attributable to foreign disposition gain or U.S. disposition loss, as applicable, even if the disposition amount exceeds the foreign disposition gain or the absolute value of the U.S. disposition loss. If the disposition results in both a foreign disposition gain and a U.S. disposition loss, the disposition amount is attributable first to foreign disposition gain to the extent thereof, and the excess disposition amount, if any, is attributable to the U.S. disposition loss, even if the excess disposition amount exceeds the absolute value of the U.S. disposition loss.

(ii) *RFA with a negative basis difference.* When there is a disposition of an RFA with a negative basis difference and the disposition results in either a foreign disposition loss or a U.S. disposition gain, but not both, the entire disposition amount is attributable to foreign disposition loss or U.S. disposition gain, as applicable, even if the absolute value of the disposition amount exceeds the absolute value of the foreign disposition loss or the U.S. disposition gain. If the disposition results in both a foreign disposition loss and a U.S. disposition gain, the disposition amount is attributable first to foreign disposition loss to the extent thereof, and the excess disposition amount, if any, is attributable to the U.S. disposition gain, even if the absolute value of the excess disposition amount exceeds the U.S. disposition gain.

(6) *U.S. taxable year of a section 901(m) payor to which an allocated cost recovery amount or disposition amount is assigned.* A cost recovery amount or a disposition amount allocated to a section 901(m) payor under paragraph (d) of this section is assigned to the U.S. taxable year of the section 901(m) payor that includes the last day of the U.S. taxable year of the RFA owner (U.S.) in which, in the case of a cost recovery amount, the RFA owner (U.S.) takes into account the corresponding U.S. basis deduction (without regard to whether the deduction is deferred or disallowed for U.S. income tax purposes), or in the case of a disposition amount, the disposition occurs.

(e) *Special rules for certain section 743(b) CAAs.* If a section 901(m) payor acquires a partnership interest in a section 743(b) CAA, including a section 743(b) CAA with respect to a lower-tier partnership that results from a direct acquisition by the section 901(m) payor of an interest in an upper-tier partnership, and subsequently there is a cost recovery amount or a disposition amount that arises from an RFA with respect to that section 743(b) CAA, all of the cost recovery amount or the disposition amount is allocated to that section 901(m) payor. The U.S. taxable year of the section 901(m) payor to which the cost recovery amount or the disposition amount is assigned is the U.S. taxable year in which, in the case of a cost recovery amount, the section 901(m) payor takes into account the corresponding U.S. basis deduction (without regard to whether the deduction is deferred or disallowed for U.S. income tax purposes), or in the case of a disposition amount, the disposition occurs.

(f) *Mid-year transactions*—(1) *In general.* When a disposition of an RFA occurs in the same foreign taxable year that a foreign payor is involved in a mid-year transaction, the portion of the disposition amount that is attributable to foreign disposition gain or foreign disposition loss (as determined under paragraph (d)(5) of this section) is allocated to a section 901(m) payor and assigned to a U.S. taxable year of the section 901(m) payor under this paragraph (f). To the extent the disposition amount is attributable to U.S. disposition gain or U.S. disposition loss (as determined under paragraph (d)(5) of this section), see paragraph (c)(1) or (d) of this section, as applicable.

(2) *Allocation rule.* To the extent a disposition amount is attributable to foreign disposition gain or foreign disposition loss, a section 901(m) payor is allocated the portion of the disposition amount equal to the product of the disposition amount attributable to foreign disposition gain or foreign disposition loss, as applicable, and a fraction, the numerator of which is the portion of the foreign disposition gain or foreign disposition loss that is included in the allocable foreign income of the section 901(m) payor, and the denominator of which is the foreign disposition gain or foreign disposition loss. If allocable foreign income is not otherwise required to be determined because there is no foreign income tax amount, the numerator is the portion of the foreign disposition gain or foreign disposition loss that would be included in the allocable foreign income of the section 901(m) payor if there were a foreign income tax amount.

(3) *Assignment to a U.S. taxable year of a section 901(m) Payor.* A disposition amount allocated to a section 901(m) payor under paragraph (f)(2) of this section is assigned to the U.S. taxable year of the section 901(m) payor in which the foreign disposition gain or foreign disposition loss (or portion thereof) is included in allocable foreign income of the section 901(m) payor or, if allocable foreign income is not otherwise required to be determined because there is no foreign income tax amount, the U.S. taxable year in which the foreign disposition gain or foreign disposition loss would be included in allocable foreign income if there were a foreign income tax amount.

(g) *Reverse hybrids*—(1) *In general.* This paragraph (g) provides rules for allocating a cost recovery amount or a disposition amount when the RFA owner (U.S.) is either a reverse hybrid

or a fiscally transparent entity for U.S. and foreign income tax purposes that is directly or indirectly owned by a reverse hybrid for U.S. and foreign income tax purposes, and in each case, the foreign payor whose foreign income includes a distributive share of the foreign income of the RFA owner (foreign) directly or indirectly owns an interest in the reverse hybrid for foreign income tax purposes. Application of the allocation rules under paragraphs (g)(2) and (g)(3) of this section depend upon whether a section 901(m) payor or a disregarded entity directly owned by a section 901(m) payor is the foreign payor, or, instead, a section 901(m) payor directly or indirectly owns an interest in the foreign payor. For purposes of this paragraph (g), unless otherwise indicated, a reference to direct or indirect ownership in an entity means for U.S. income tax purposes. For purposes of this paragraph (g), a person indirectly owns an interest in an entity for U.S. income tax purposes if the person owns the interest through one or more fiscally transparent entities for U.S. income tax purposes, and at least one of the fiscally transparent entities is not a disregarded entity . For purposes of this paragraph (g), a person indirectly owns an interest in an entity for foreign income tax purposes if the person owns the interest through one or more fiscally transparent entities for foreign income tax purposes. If the RFA owner (U.S.) is a lower-tier fiscally transparent entity for U.S. income tax purposes in which the reverse hybrid indirectly owns an interest, the rules of this section apply in a manner consistent with the application of these rules when the reverse hybrid directly owns an interest in the RFA owner (U.S.).

(2) *First allocation rule*—(i) *Allocation to a section 901(m) payor.* This paragraph (g)(2)(i) applies when a section 901(m) payor, or a disregarded entity directly owned by a section 901(m) payor, is the foreign payor whose foreign income includes a distributive share of the foreign income of the RFA owner (foreign), and, therefore, all of the foreign income tax amount of the foreign payor is paid or accrued by, or considered paid or accrued by, the section 901(m) payor. Thus, this paragraph (g)(2)(i) applies when a section 901(m) payor either directly owns an interest in the reverse hybrid or directly owns an interest in a fiscally transparent entity for U.S. and foreign income tax purposes, which, in turn, directly or indirectly owns an interest in the reverse hybrid for both U.S. and foreign income tax purposes. In these cases, the section 901(m) payor is allocated the portions of cost recovery amounts or disposition amounts (or both) with respect to RFAs that are equal to the product of the sum of the cost recovery amounts and the disposition amounts and a fraction, the numerator of which is the portion of the foreign income of the RFA owner (foreign) that is included in the foreign income of the foreign payor, and the denominator of which is the foreign income of the RFA owner (foreign).

(ii) *Assignment to a U.S. taxable year of a section 901(m) Payor.* This paragraph (g)(2)(ii) applies when a cost recovery amount or a disposition amount, or portion thereof, is allocated to a section 901(m) payor under paragraph (g)(2)(i) of this section. If the reverse hybrid is the RFA owner (U.S.), a cost recovery amount or disposition amount, or portion thereof, is assigned to the U.S. taxable year of the section 901(m) payor that includes the last day of the U.S. taxable year of the reverse hybrid in which, in the case of a cost recovery amount, the reverse hybrid takes into account the corresponding U.S. basis deduction (without regard to whether the deduction is deferred or disallowed for U.S. income tax purposes), or, in the case of a disposition amount, the disposition occurs. If the reverse hybrid is not the RFA owner (U.S.) but instead the reverse hybrid directly or indirectly owns an interest in the RFA owner (U.S.) for both U.S. and foreign income tax purposes, a cost recovery amount or disposition amount, or portion thereof, is assigned to the U.S. taxable year of the section 901(m) payor that includes the last day of the U.S. taxable year of the reverse hybrid, which, in turn, includes the last day of the U.S. taxable year of the RFA owner (U.S.) in which, in the case of a cost recovery amount, the RFA owner (U.S.) takes into account the corresponding U.S. basis deduction (without regard to whether the deduction is deferred or disallowed for U.S. income tax purposes), or, in the case of a disposition amount, the disposition occurs.

(3) *Second allocation rule*—(i) *Allocation to a section 901(m) payor.* This paragraph (g)(3)(i) applies when neither a section 901(m) payor nor a disregarded entity directly owned by a section 901(m) payor is the foreign payor with respect to the foreign income of the RFA owner (foreign). Instead, a section 901(m) payor directly or indirectly owns an interest in the foreign payor, which is a fiscally transparent entity for U.S. income tax purposes (other than a disregarded entity directly owned by the section 901(m) payor), and, therefore, the section 901(m) payor is considered to pay or accrue only its allocated portion of the foreign income tax amount of the foreign payor. In these cases, the section 901(m) payor is allocated the portions of cost recovery amounts or disposition amounts (or both) with respect to RFAs that are equal to the product of the sum of the cost recovery amounts and the disposition amounts and a fraction, the numerator of which is the portion of the foreign income of the RFA owner (foreign) that is included in the foreign income of the foreign payor and included in the allocable foreign income of the section 901(m) payor, and the denominator of which is the foreign income of the RFA owner (foreign). If allocable foreign income is not otherwise required to be determined for a section 901(m) payor because there is no foreign income tax amount, the numerator is the foreign income of the RFA owner (foreign) that is included in the foreign income of the foreign payor and that would be included in allocable foreign income of the section 901(m) payor if there were a foreign income tax amount.

(ii) *Assignment to a U.S. taxable year of a section 901(m) payor.* A cost recovery amount or a disposition amount, or portion thereof, that is allocated to a section 901(m) payor under paragraph (g)(3)(i) of this section is assigned to the U.S. taxable year of the section 901(m) payor in which the foreign income of the RFA owner (foreign) described in paragraph (g)(3)(i) of this section is included in the allocable foreign income of the section 901(m) payor, or, if there is no foreign income tax amount, the U.S. taxable year of the section 901(m) payor in which the foreign income of the RFA owner (foreign) described in paragraph (g)(3)(i) of this section would be included in allocable foreign income if there were a foreign income tax amount.

(h) *Examples.* The following examples illustrate the rules of this section. In addition to any facts described in a particular example, the following facts apply to all the examples unless otherwise specified: CFC1, CFC2, and DE are organized in Country F and treated as corporations for Country F tax purposes. CFC1 and CFC2 are each a section 902 corporation (as defined in section 909(d)(5)) that is wholly owned by the same U.S. corporation, and DE is a disregarded entity . CFC1 and CFC2 have a U.S. taxable year that is a calendar year, and CFC1, CFC2, and DE have a foreign taxable year that is a calendar year. Country F imposes a single tax that is a foreign income tax . CFC1, CFC2, and DE each have a functional currency of the u with

respect to all activities. At all relevant times, 1u equals $1. All amounts are stated in millions. The examples assume that the applicable cost recovery method for property results in basis being recovered ratably over the life of the property beginning on the first day of the U.S. taxable year in which the property is acquired or placed into service.

Example 1. CAA followed by disposition: fully taxable for both U.S. income tax and foreign income tax purposes—(i) *Facts.* (A) On January 1, Year 1, USP acquires all of the stock of CFC1 in a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies (Section 338 Acquisition). At the time of the Section 338 Acquisition, CFC1 owns a single asset (Asset A) that is located in Country F. Asset A gives rise to income that is taken into account for Country F tax purposes. Asset A is tangible personal property that, under the applicable cost recovery method in the hands of CFC1, is depreciable over 5 years. There are no cost recovery deductions available for Country F tax purposes with respect to Asset A. Immediately before the Section 338 Acquisition, Asset A has a U.S. basis of 10u and a foreign basis of 40u. Immediately after the Section 338 Acquisition, Asset A has a U.S. basis of 100u and foreign basis of 40u.

(B) On July 1, Year 2, Asset A is transferred to an unrelated third party in exchange for 120u in a transaction in which all realized gain is recognized for both U.S. income tax and Country F tax purposes (subsequent transaction). For U.S. income tax purposes, CFC1 recognizes U.S. disposition gain of 50u (amount realized of 120u, less U.S. basis of 70u (100u cost basis, less 30u of accumulated depreciation)) with respect to Asset A. The 30u of accumulated depreciation is the sum of 20u of depreciation in Year 1 (100u cost basis/5 years) and 10u of depreciation in Year 2 ((100u cost basis/5 years) × 6/12). For Country F tax purposes, CFC1 recognizes foreign disposition gain of 80u (amount realized of 120u, less foreign basis of 40u) with respect to Asset A. Immediately after the subsequent transaction, Asset A has a U.S. basis and a foreign basis of 120u.

(ii) *Result.* (A) Under § 1.901(m)–2(b)(1), USP's acquisition of the stock of CFC1 in the Section 338 Acquisition is a section 338 CAA. Under § 1.901(m)–2(c)(i), Asset A is an RFA with respect to Country F tax because it is relevant in determining the foreign income of CFC1 for Country F tax purposes. Under § 1.901(m)–4(b), the basis difference with respect to Asset A is 90u (100u − 10u). Under Section 901(m)–1(a)(31), CFC1 is the RFA owner (U.S.) with respect to Asset A. Under § 1.901(m)–1(a)(23), CFC1 is a foreign payor for Country F tax purposes. Under § 1.901(m)–1(a)(35), CFC1 is the section 901(m) payor with respect to a foreign income tax amount for which CFC1 is the foreign payor (see § 1.901–2(f)(1)).

(B) Under § 1.901(m)–1(a)(5), allocated basis differences are comprised of cost recovery amounts and disposition amounts. In Year 1, Asset A has an allocated basis difference that includes only a cost recovery amount. Under paragraph (b)(2) of this section, the cost recovery amount for Year 1 is determined by applying the applicable cost recovery method of Asset A in the hands of CFC1 to the basis difference with respect to Asset A. Accordingly the cost recovery amount is 18u (90u basis difference/5 years). Under paragraph (b)(1) of this section, all of the 18u cost recovery amount is attributed to CFC1 and assigned to Year 1, because CFC1 is a section 901(m) payor and RFA owner (U.S.) with respect to Asset A and Year 1 is the U.S. taxable year of CFC1 in which it takes into account the corresponding 20u of depreciation. Immediately after Year 1, under § 1.901(m)–1(a)(40), unallocated basis difference is 72u with respect to Asset A (90u − 18u).

(C) In Year 2, Asset A has an allocated basis difference that includes both a cost recovery amount and a disposition amount. Under paragraph (b)(2) of this section, the cost recovery amount for Year 2, as of the date of the subsequent transaction, is 9u ((90u basis difference/5 years) × 6/12). Under § 1.901(m)–1(a)(10), the subsequent transaction is a disposition of Asset A, because the subsequent transaction is an event that results in an amount of gain being recognized for U.S. income tax and Country F tax purposes. Because all realized gain in Asset A is recognized for U.S. income tax and Country F tax purposes, the rule in paragraph (c)(2)(i) of this section applies to determine the disposition amount. Under that rule, the disposition amount for Year 2 is the unallocated basis difference of 63u (90u basis difference, less total 27u taken into account as cost recovery amounts in Year 1 and Year 2). Accordingly, the allocated basis difference for Year 2 is 72u (9u of cost recovery amount, plus 63u of disposition amount). Under paragraphs (b)(1) and (c)(1) of this section, all of the 72u of allocated basis difference is attributed to CFC1 and assigned to Year 2, because CFC1 is a section 901(m) payor and the RFA owner (U.S.) with respect to Asset A and Year 2 is the U.S. taxable year of CFC1 in which it takes into account the corresponding 10u of depreciation and in which the disposition occurred.

(D) Unallocated basis difference with respect to Asset A, as determined immediately after the subsequent transaction, is 0u (90u basis difference less 90u basis difference taken into account as 27u total cost recovery amount in Year 1 and Year 2 and as a 63u disposition amount in Year 2). Accordingly, because there is no unallocated basis difference with respect to Asset A attributable to the Section 338 Acquisition, the subsequent transaction is not a successor transaction as defined in § 1.901(m)–6(b)(2). Furthermore, the subsequent transaction is not a CAA under § 1.901(m)–2(b). For these reasons, section 901(m) no longer applies to Asset A.

Example 2. CAA followed by Disposition: nontaxable for U.S. income tax purposes and taxable for foreign income tax purposes—(i) *Facts.* The facts are the same as in paragraph (i)(A) of *Example 1* but the facts in paragraph (i)(B) of *Example 1* are instead that on July 1, Year 2, Asset A is transferred to CFC2, in exchange for 100u of stock of CFC2 (subsequent transaction). For U.S. income tax purposes, CFC1 does not recognize any U.S. disposition gain or U.S. disposition loss with respect to Asset A. For Country F tax purposes, CFC1 recognizes foreign disposition gain of 60u (amount realized of 100u, less foreign basis of 40u) with respect to Asset A. Immediately after the subsequent transaction, Asset A has a U.S. basis of 70u (100u cost basis less 30u accumulated depreciation) and a foreign basis of 100u. The 30u of accumulated depreciation is the sum of 20u of depreciation in Year 1 (100u cost basis/5 years) and 10u in Year 2 ((100u cost basis/5 years) x 6/12).

(ii) *Result.* (A) The results described in paragraph (ii)(A) of *Example 1* also apply to this *Example 2.*

(B) The result for Year 1 is the same as in paragraph (ii)(B) of *Example 1.*

(C) In Year 2, Asset A has an allocated basis difference that includes both a cost recovery amount and a disposition amount. Under paragraph (b)(2) of this section, the cost recovery amount for Year 2, as of the date of the subsequent transaction, is 9u ((90u basis difference/5 years) × 6/12). Under § 1.901(m)–1(a)(10), the Transaction is a disposition of Asset A, because the subsequent transaction is an event that results in an amount of gain being recognized for Country F tax purposes. Because the disposition is not also fully taxable for U.S. income tax purposes, the rule in paragraph (c)(2)(ii) of this section applies to determine the disposition amount. Under that rule, the disposition amount is 60u, the lesser of (i) 60u (60u foreign disposition gain plus absolute value of 0u U.S. disposition loss), and (ii) 63u unallocated basis difference (90 basis difference less total 27u taken into account as cost recovery amounts, 18u in Year 1 and 9u in Year 2). Accordingly, the allocated basis difference for the first half of Year 2 is 69u (9u of cost recovery amount, plus 60u of disposition amount). Under paragraphs (b)(1) and (c)(1) of this section, all of the 69u of allocated basis difference is attributed to CFC1 and assigned to Year 2, because CFC1 is a section 901(m) payor and the RFA owner (U.S.) with respect to Asset A and Year 2 is the U.S. taxable year of CFC1 in which it takes into account the corresponding 10u of depreciation and in which the disposition occurred.

(D) Unallocated basis difference with respect to Asset A immediately after the subsequent transaction is 3u (90u basis difference less 87u basis difference taken into account as a 27u total cost recovery amount in Year 1 and Year 2 and as a 60u disposition amount in Year 2). Accordingly, because there is unallocated basis difference of 3u with respect to Asset A attributable to the Section 338 Acquisition, as determined immediately after the subsequent transaction, the subsequent transaction is a successor transaction as defined in § 1.901(m)–6(b)(2). Following the subsequent transaction, the unallocated basis difference of 3u must be taken into account as cost recovery amounts or disposition amounts (or both) by CFC2, the new section 901(m) payor and RFA owner (U.S.) of Asset A. See § 1.901(m)–6(b)(3)(ii). Because the subsequent transaction is not a CAA under § 1.901(m)–2(b), there is no additional basis difference with respect to Asset A as a result of the subsequent transaction.

Example 3. CAA followed by disposition: nontaxable for both U.S. income tax and foreign income tax purposes—(i) *Facts.* The facts are the same as in paragraph (i)(A) of *Example 1* but the facts in paragraph (i)(B) of *Example 1* are instead that on July 1, Year 2, CFC1 transfers Asset A to CFC2, in exchange for 110u of stock of CFC2 (subsequent transaction). For U.S. income tax purposes, CFC1 does not recognize any U.S. disposition gain or U.S. disposition loss with respect to Asset A as a result of the subsequent transaction. Furthermore, for Country F tax purposes, CFC1 recognizes no foreign disposition gain or foreign disposition loss with respect to Asset A as a result of the subsequent transaction. Immediately after the subsequent transaction, Asset A has a U.S. basis of 70u (100u cost basis less 30u accumulated depreciation) and a foreign basis of 40u. The 30u of accumulated depreciation is the sum of 20u of depreciation in Year 1 (100u cost basis/5 years) and 10u in Year 2 ((100u cost basis/5 years) × 6/12).

(ii) *Result.* (A) The result for Year 1 is the same as in paragraph (ii)(A) of *Example 1.*

(B) The result for Year 1 is the same as in paragraph (ii)(B) of *Example 1.*

(C) In Year 2, Asset A has an allocated basis difference that includes only a cost recovery amount. Under paragraph (b)(2) of this section, the cost recovery amount for Year 2, as of the date of the subsequent transaction, is 9u ((90u basis difference/5 years) × 6/12). Under § 1.901(m)–1(a)(10), the subsequent transaction does not constitute a disposition of Asset A, because the subsequent transaction is not an event that results in an amount of gain or loss being recognized for U.S. income tax or for Country F tax purposes. Therefore, no disposition amount is taken into account for Asset A in Year 2. Under paragraph (b)(1) of this section, all of the 9u of allocated basis difference is attributed to CFC1 and assigned to Year 2, because CFC1 is a section 901(m) payor and RFA owner (U.S.) with respect to Asset A and Year 2 is the U.S. taxable year of CFC1 in which it takes into account the corresponding 10u of depreciation.

(D) Unallocated basis difference with respect to Asset A immediately after the subsequent transaction is 63u (90u basis difference, less 27u total cost recovery amounts, 18u in Year 1 and 9u in Year 2). Accordingly, because there is unallocated basis difference of 63u with respect to Asset A attributable to the CAA, as determined immediately after the subsequent transaction, the subsequent transaction is a successor transaction as defined in § 1.901(m)–6(b)(2). Following the subsequent transaction, the unallocated basis difference of 63u must be taken into account as cost recovery amounts or disposition amounts (or both) by CFC2, the new section 901(m) payor and RFA owner (U.S.) of Asset A. See § 1.901(m)–6(b)(3)(ii). Because the subsequent transaction is not a CAA under § 1.901(m)–2(b), there is no additional basis difference with respect to Asset A as a result of the subsequent transaction.

(i) *Effective/applicability date.* (1) Except for paragraphs (b)(2)(i) and (c)(2) of this section, this section applies to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(2) [The text of proposed § 1.901(m)–5(i)(2) is the same as the text of § 1.901(m)–5T(i)(2) published elsewhere in this issue of the **Federal Register**.]

(3) Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section, § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, § 1.901(m)–3, § 1.901(m)–4 (excluding § 1.901(m)–4(e)), § 1.901(m)–6, § 1.901(m)–7, and § 1.901(m)–8 to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 8.** Section 1.901(m)–6 is added to read as follows:

§ 1.901(m)–6 Successor rules.

(a) through (b)(2) [The text of proposed §§ 1.901(m)–6(a) through (b)(2) is the same as the text of §§ 1.901(m)–6T(a) through (b)(2) published elsewhere in this issue of the **Federal Register**.]

(3) *Special considerations.* (i) If an asset is an RFA with respect to more than one foreign income tax, this paragraph (a) applies separately with respect to each foreign income tax.

(ii) Any subsequent cost recovery amount for an RFA transferred in a successor transaction is determined based on the post-transaction applicable cost recovery method, as described in § 1.901(m)–5(b)(3), that applies to the U.S. basis (or portion thereof) that corresponds to the unallocated basis difference.

(4)(i) [The text of proposed § 1.901(m)–6(b)(4)(i) is the same as the text of § 1.901(m)–6T(b)(4)(i) published elsewhere in this issue of the **Federal Register**.]

(ii) *Foreign basis election.* If a foreign basis election is made under § 1.901(m)–4(c) with respect to a foreign income tax in a subsequent CAA, any unallocated basis difference with respect to one or more prior CAAs will not be taken into account under section 901(m). The only basis difference that will be taken into account after the subsequent CAA with respect to that foreign income tax is the basis difference with respect to the subsequent CAA.

(b)(4)(iii) [The text of proposed § 1.901(m)–6(b)(4)(iii) is the same as the text of § 1.901(m)–6T(b)(4)(iii) published elsewhere in this issue of the **Federal Register**.]

(5) [The text of proposed § 1.901(m)–6(b)(5) is the same as the text of § 1.901(m)–6T(b)(5) published elsewhere in this issue of the **Federal Register**.]

(c) *Successor rules for aggregate basis difference carryover*—(1) *Transfers of a section 901(m) payor's aggregate basis difference carryover to another person.* If a corporation acquires the assets of a section 901(m) payor in a transaction to which section 381 applies, that corporation succeeds to any aggregate basis difference carryovers of the section 901(m) payor.

(2) *Transfers of a section 901(m) payor's aggregate basis difference carryover with respect to a foreign payor to another foreign payor.* If a section 901(m) payor has an aggregate basis difference carryover, with respect to a foreign income tax and a foreign payor, and substantially all of the assets of the foreign payor are transferred to another foreign payor in which the section 901(m) payor owns an interest, the section 901(m) payor's aggregate basis difference carryover with respect to the first foreign payor is transferred to the section 901(m) payor's aggregate basis difference carryover with respect to the other foreign payor. In such a case, the section 901(m) payor's aggregate basis difference carryover with respect to the first foreign payor is reduced to zero.

(3) *Anti-abuse rule.* If a section 901(m) payor has an aggregate basis difference carryover with respect to a foreign income tax and a foreign payor and, with a principal purpose of avoiding the application of section 901(m), assets of the foreign payor are transferred to another foreign payor in a transaction not described in paragraph (c)(1) or (2) of this section, then a portion of the aggregate basis difference carryover of the section 901(m) payor is transferred either to the aggregate basis difference carryover of the section 901(m) payor with respect to the other foreign payor or to another section 901(m) payor, as appropriate. The portion of the aggregate basis difference carryover transferred is determined based on the ratio of fair market value of the assets transferred to the fair market value of all of the assets of the foreign payor that transferred the assets. Similar principles apply when, with a principle purpose of avoiding the application of section 901(m), there is a change in the allocation of foreign income for foreign income tax purposes or the allocation of foreign income tax amounts for U.S. income tax purposes that would otherwise separate foreign income tax

amounts from the related aggregate basis difference carryover.

(4) *Ownership.* For purposes of this paragraph (c), a section 901(m) payor owns an interest in a foreign payor if the section 901(m) payor owns the interest directly or indirectly through one or more fiscally transparent entities for U.S. income tax purposes.

(d) *Effective/applicability date.* (1) [The text of proposed § 1.901(m)–6(d)(1) is the same as the text of § 1.901(m)–6T(d)(1) published elsewhere in this issue of the **Federal Register**.]

(2) Paragraphs (b)(3), (b)(4)(ii), and (c) of this section apply to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

(3) Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section, § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, §§ 1.901(m)–3 through 1.901(m)–5 (excluding § 1.901(m)–4(e)), § 1.901(m)–7, and § 1.901(m)–8 to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 9.** Section 1.901(m)–7 is added to read as follows:

§ 1.901(m)–7 De minimis rules.

(a) *In general.* This section provides rules describing basis difference that is not taken into account under section 901(m) because a CAA results in a de minimis amount of basis difference. Paragraph (b) of this section sets forth the general rule for determining whether the de minimis threshold is met. Paragraph (c) of this section provides modifications to the general rule in the case of CAAs involving related persons and CAAs that are part of an aggregated CAA transaction. Paragraph (d) of this section provides rules for applying this section, and paragraph (e) of this section provides an anti-abuse rule applicable to related persons. Paragraph (f) of this section provides examples that illustrate the application of this section. Paragraph (g) of this section provides the effective/applicability date.

(b) *General rule*—(1) *In general.* A basis difference with respect to an RFA and a foreign income tax is not taken into account under section 901(m) if the requirements under either the cumulative basis difference exemption or the RFA class exemption are satisfied.

(2) *Cumulative basis difference exemption.* Except as provided in paragraph (c) of this section, a basis difference, with respect to an RFA and a foreign income tax, is not taken into account under section 901(m) (cumulative basis difference exemption) if the sum of that basis difference and all other basis differences (including negative basis differences), with respect to a single CAA and a single RFA owner (U.S.), is less than the greater of:

(i) $10 million, or

(ii) 10 percent of the total U.S. basis of all the RFAs immediately after the CAA.

(3) *RFA class exemption*—(i) Except as provided in paragraph (c) of this section, a basis difference, with respect to an RFA and a foreign income tax, is not taken into account under section 901(m) (RFA class exemption) if the RFA is part of a class of RFAs and the absolute value of the sum of the basis differences (including negative basis differences), with respect to a single CAA and a single RFA owner, for all the RFAs in that class is less than the greater of:

(A) $2 million, or

(B) 10 percent of the total U.S. basis of all the RFAs in that class of RFAs immediately after the CAA.

(ii) For purposes of this paragraph (b)(3), the classes of RFAs are the seven asset classes defined in § 1.338–6(b), regardless of whether the CAA is a section 338 CAA.

(c) *Special rules*—(1) *Modification of de minimis rules for related persons.* If the transferor and transferee in the CAA are related persons (as described in section 267(b) or 707(b)), the cumulative basis difference exemption and the RFA class exemption, as described in paragraph (b) of this section, are applied by replacing the terms ''$10 million,'' ''10 percent'', and ''$2 million'' wherever they occur in that paragraph with the terms ''$5 million,'' ''5 percent,'' and ''$1 million,'' respectively.

(2) *CAA part of an aggregated CAA transaction.* If a CAA is part of an aggregated CAA transaction and a single RFA owner (U.S.) does not own all the RFAs attributable to the CAAs that are part of the aggregated CAA transaction, the cumulative basis difference exemption and the RFA class exemption apply to such CAA only if, in addition to satisfying the requirements of paragraph (b)(2) or (b)(3) of this section, respectively, determined without regard to this paragraph (c)(2), the cumulative basis difference exemption or the RFA class exemption, as modified by this paragraph (c)(2), is satisfied. Solely for purposes of this paragraph (c)(2), the cumulative basis difference exemption and the RFA class exemption are applied taking into account all the basis differences with respect to all the RFAs owned by all the RFA owners (U.S.) that are attributable to the CAAs that are part of the aggregated CAA transaction.

(d) *Rules of application.* The following rules apply for purposes of this section.

(1) Whether a basis difference qualifies for the cumulative basis difference exemption or the RFA class exemption is determined when an asset first becomes an RFA with respect to a CAA. In the case of a subsequent CAA described in § 1.901(m)–6(b)(4), the application of the cumulative basis difference exemption and the RFA class exemption is based on basis difference, if any, that results from the subsequent CAA.

(2) If there is an aggregated CAA transaction, the cumulative basis difference exemption and each RFA class exemption are applied by treating all CAAs that are part of the aggregated CAA transaction as a single CAA.

(3) Basis difference is computed in accordance with § 1.901(m)–4 except that a foreign basis election need not be evidenced if either the cumulative basis difference exemption or an RFA class exemption apply to all RFAs with respect to the CAA.

(4) Basis difference is translated into U.S. dollars (if necessary) using the spot rate determined under the principles of § 1.988–1(d) on the date of the CAA.

(e) *Anti-abuse rule.* The cumulative basis difference exemption and an RFA class exemption are not available if the transferor and transferee in the CAA are related persons (as described in section 267(b) or 707(b)) and the CAA was entered into, or structured, with a principal purpose of avoiding the application of section 901(m). See also § 1.901(m)–8(c), which provides that certain built-in loss assets are not taken into account for purposes of applying this section.

(f) *Examples.* The following examples illustrate the rules of this section:

Example 1. De minimis; cumulative basis difference exemption—(i) *Facts.* USP, a domestic corporation, as part of a plan, purchases all of the stock of CFC1 and CFC2 from a single seller. CFC1 and CFC2 are section 902 corporations (as defined in section 909(d)(5)), organized in Country F, and treated as corporations for Country F tax purposes. Country F imposes a single tax that is a foreign income tax . Each acquisition is a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies. A foreign basis election is not made under § 1.901(m)–4(c). Immediately after the acquisition of the stock of CFC1 and CFC2, the assets of CFC1 and CFC2 give rise to

income that is taken into account for Country F tax purposes, and those assets are in a single class, as defined in § 1.338–6(b). At all relevant times, 1u equals $1. All amounts are stated in millions. The additional facts are summarized below.

Relevant foreign assets	Total U.S. basis immediately before	Total U.S. basis immediately after	Total basis difference
Assets of CFC1	48u	60u	12u
Assets of CFC2	100u	96u	(4)u
Total	148u	156u	8u

(ii) *Result.* (A) Under § 1.901(m)–2(b)(1), USP's acquisitions of the stock of CFC1 and CFC2 are each a section 338 CAA. Under 1.901(m)–1(a)(3), the two section 338 CAAs constitute an aggregated CAA transaction because the acquisitions occur as part of a plan. Under § 1.901(m)–2(c)(1), the assets of CFC1 and CFC2 are RFAs for Country F tax purposes because they are relevant in determining foreign income of CFC1 and CFC 2, respectively, for Country F tax purposes. Under § 1.901(m)–1(a)(31), CFC1 is the RFA owner (U.S.) with respect to its assets, and CFC2 is the RFA owner (U.S.) with respect to its assets.

(B) Under paragraph (b)(2) of this section, the application of the cumulative basis difference exemption is based on a single CAA and a single RFA owner (U.S.), subject to the requirements under paragraph (c)(2) of this section that apply when there is an aggregated CAA transaction. In the case of the section 338 CAA with respect to CFC1, without regard to paragraph (c)(2) of this section, the requirements of the cumulative basis difference exemption are satisfied if the sum of the basis differences is less than the threshold of $10 million, the greater of $10 million or $6 million (10% of the total U.S. basis of $60 million (60 million u translated into dollars at the exchange rate of $1 = 1u)). In this case, the sum of the basis differences is $12 million (12 million u translated into dollars at the exchange rate of $1 = 1 u). Because the sum of the basis differences of $12 million is not less than the threshold of $10 million, the requirements of the cumulative basis difference exemption are not satisfied. Because the requirements of the cumulative basis difference exemption are not satisfied, without regard to paragraph (c)(2) of this section, paragraph (c)(2) of this section is not applicable. Finally, the RFA class exemption is not relevant because all of the RFAs of CFC1 are in a single class. Accordingly, the basis differences with respect to all of the RFAs of CFC1 must be taken into account under section 901(m).

(C) In the case of the section 338 CAA with respect to CFC2, without regard to paragraph (c)(2) of this section, the requirements of the cumulative basis difference exemption are satisfied if the sum of the basis differences is less than the threshold of $10 million, the greater of $10 million or $ 9.6 million (10% of the total U.S. basis of $96 million (96 million u translated into dollars at the exchange rate of $1 = 1u)) In this case, the sum of the basis differences is ($4) million ((4) million u translated into dollars at the exchange rate of $1 = 1 u). Because the sum of the basis differences of ($4) million is less than the threshold of $10 million, the requirements of the cumulative basis difference exemption are satisfied. However, because the section 338 CAA with respect to CFC2 is part of an aggregate CAA transaction that includes the section 338 CAA with respect to CFC1, paragraph (c)(2) of this section is applicable. Under paragraph (c)(2) of this section, the requirements of the cumulative basis difference exemption must also be satisfied taking into account all of the RFAs of both CFC2 and CFC1. In this case, the requirements of the cumulative basis difference exemption for purposes of paragraph (c)(2) of this section are satisfied if the sum of the basis differences with respect to all of the RFAs of CFC2 and CFC1 is less than the threshold of $15.6 million, the greater of $10 million or $15.6 million (10% of the total U.S. basis of $156 million (156 million u translated into dollars at the exchange rate of $1 = 1u)) In this case, the sum of the basis differences is $8 million (8 million u translated into dollars at the exchange rate of $1 = 1 u). Because the sum of the basis differences of $8 million is less than the threshold of $15.6 million, the requirements of the cumulative basis difference exemption are satisfied in the case of the section 338 CAA with respect to CFC2. Accordingly, none of the basis differences with respect to the RFAs of CFC2 are taken into account under section 901(m).

Example 2. De minimis; RFA Class Exemption—(i) *Facts.* USP, a domestic corporation, acquires all the stock of CFC, a section 902 corporation (as defined in section 909(d)(5)) organized in Country F and treated as a corporation for Country F tax purposes, in a qualified stock purchase (as defined in section 338(d)(3)) to which section 338(a) applies. Country F imposes a single tax that is a foreign income tax . A foreign basis election is not made under § 1.901(m)–4(c). Immediately after the acquisition of CFC, the assets of CFC give rise to income that is taken into account for Country F tax purposes. At all relevant times, 1u equals $1. All amounts are stated in millions. The additional facts are summarized below.

Relevant foreign assets	Total U.S. basis immediately before	Total U.S. basis immediately after	Total basis difference
Cash (Class I)	10u	10u	0u
Inventory (Class IV)	14u	15u	1u
Buildings (Class V)	19u	30u	11u
Total	43u	55u	12u

(ii) *Result.* (A) Under § 1.901(m)–2(b)(1), USP's acquisition of the stock of CFC is a section 338 CAA. Under § 1.901(m)–2(c)(1), the assets of CFC are RFAs for Country F tax purposes because they are relevant in determining foreign income of CFC for Country F tax purposes.

(B) Under paragraph (b)(2) of this section, the requirements of the cumulative basis difference exemption are satisfied if the sum of the basis differences is less than the threshold of $10 million, the greater of $10 million or $5.5 million (10% of the total U.S. basis of $55 million (55 million u translated into dollars at the exchange rate of $1 = 1u)). In this case, the sum of the basis differences is $12 million (12 million u translated into dollars at the exchange rate of $1 = 1 u). Because the sum of the basis differences of $12 million is not less than the threshold of $10 million, the requirements of the cumulative basis difference exemption are not satisfied.

(C) Under paragraph (b)(3) of this section, each of CFC's assets is allocated to its class under § 1.338–6(b) for purposes of the RFA class exemption. The requirements of the RFA class exemption with respect to the Class IV RFAs (in this case, inventory) are satisfied if the absolute value of the sum of the basis differences with respect to the Class IV RFAs is less than the threshold of $2

million, the greater of $2 million or $1.5 million (10% of the total U.S. basis of Class IV RFAs of $15 million (15 million u translated into dollars at the exchange rate of $1 = 1u)) In this case, the absolute value of the sum of the basis differences is $1 million (1 million u translated into dollars at the exchange rate of $1 = 1 u). Because the sum of the basis differences of $1 million is less than the threshold of $2 million, the requirements of the RFA class exemption are satisfied. Accordingly, the basis differences with respect to the Class IV RFAs are not taken into account under section 901(m).

(D) The requirements of the RFA class exemption with respect to the Class V RFAs (in this case, buildings) is satisfied if the absolute value of the sum of the basis differences with respect to the Class V RFAs is less than the threshold of $3 million, the greater of $2 million or $3 million (10% of the total U.S. basis of Class V RFAs of $30 million (30 million u translated into dollars at the exchange rate of $1 = 1u)). In this case, the absolute value of the sum of the basis differences is $11 million (11 million u translated into dollars at the exchange rate of $1 = 1 u). Because the sum of the basis differences of $11 million is not less than the threshold of $3 million, the requirements of the RFA class exemption are not satisfied. Accordingly, the basis differences with respect to the Class V RFAs are taken into account under section 901(m).

(E) The Class I RFAs (in this case, cash) are irrelevant because there is no basis differences with respect to those RFAs.

(g) *Effective/applicability date.* This section applies to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section, § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, §§ 1.901(m)–3 through 1.901(m)–6 (excluding § 1.901(m)–4(e)), and § 1.901(m)–8 to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

■ **Par. 10.** Section 1.901(m)–8 is added to read as follows:

§ 1.901(m)–8 Miscellaneous.

(a) *In general.* This section provides guidance on other matters under section 901(m). Paragraph (b) of this section provides guidance on the application of section 901(m) to pre-1987 foreign income taxes. Paragraph (c) of this section provides anti-abuse rules relating to built-in loss assets. Paragraph (d) of this section provides the effective/applicability date.

(b) *Application of section 901(m) to pre-1987 foreign income taxes.* Section 901(m) and §§ 1.901(m)–1 through -8 apply to pre-1987 foreign income taxes (as defined in § 1.902–1(a)(10)(iii)) of a section 902 corporation.

(c) *Anti-abuse rule for built-in loss RFAs.* A basis difference with respect to an RFA described in section 901(m)(3)(C)(ii) (built-in loss RFA) will not be taken into account for purposes of computing an allocated basis difference for a U.S. taxable year of a section 901(m) payor if any RFA, including an RFA other than built-in loss RFAs, is acquired with a principal purpose of using one or more built-in loss RFAs to avoid the application of section 901(m). Furthermore, a basis difference with respect to a built-in loss RFA will not be taken into account for purposes of the cumulative basis difference exemption or the RFA class exemption under § 1.901(m)–7 if any RFAs, including RFAs other than built-in loss RFAs, are acquired with a principal purpose of avoiding the application of section 901(m).

(d) *Effective/applicability date.* This section applies to CAAs occurring on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. Taxpayers may, however, rely on this section prior to the date this section is applicable provided that they both consistently apply this section, § 1.704–1(b)(4)(viii)(*c*)(*4*)(*v*) through (*vii*), § 1.901(m)–1, and §§ 1.901(m)–3 through 1.901(m)–7 (excluding § 1.901(m)–4(e)) to all CAAs occurring on or after January 1, 2011, and consistently apply § 1.901(m)–2 (excluding § 1.901(m)–2(d)) to all CAAs occurring on or after December 7, 2016. For this purpose, persons that are related (within the meaning of section 267(b) or 707(b)) will be treated as a single taxpayer.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

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Part VII

Department of the Treasury

31 CFR Part 50

Terrorism Risk Insurance Program; Certification; Final Rule

DEPARTMENT OF THE TREASURY

31 CFR Part 50

RIN 1505–AC53

Terrorism Risk Insurance Program; Certification

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Interim final rule with request for comment.

SUMMARY: The Department of the Treasury (Treasury) is issuing this interim final rule as part of its implementation of changes to the Terrorism Risk Insurance Program (Program) required by the Terrorism Risk Insurance Program Reauthorization Act of 2015 (2015 Reauthorization Act). This interim final rule only addresses the process for certification of an act of terrorism, as published in proposed form on April 1, 2016, for public comment. Some clarifying changes have been made in this interim final rule in response to comments, and certain wording changes have also been made which are not intended to change the meaning of the rule as originally proposed.

The proposed rule includes a more general revision to and renumbering of the Program rules which will be issued in full at a later date. Accordingly, for now, the new subpart is renumbered to avoid duplication with the existing rule numbers. Upon issuance of the final rules for the Program, the final rules will reflect the numbering sequence in the notice of proposed rulemaking published on April 1, 2016.

DATES: *Effective date:* January 6, 2017. Written comments on this interim final rule must be received on or before January 6, 2017.

ADDRESSES: Submit comments electronically through the Federal eRulemaking Portal: *http://www.regulations.gov,* or by mail (if hard copy, preferably an original and two copies) to the Federal Insurance Office, Attention: Richard Ifft, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. Because postal mail may be subject to processing delay, it is recommended that comments be submitted electronically. All comments should be captioned with ''Terrorism Risk Insurance Program Certification Comments.'' Please include your name, group affiliation, address, email address and telephone number(s) in your comment. Where appropriate, a comment should include a short Executive Summary (no more than five single-spaced pages).

In general, comments received will be posted on *http://www.regulations.gov* without change, including any business or personal information provided. Comments received, including attachments and other supporting materials, will be part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–2922 (not a toll free number) or Kevin Meehan, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–7009 (not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Terrorism Risk Insurance Act of 2002 (the Act or TRIA) [1] was enacted on November 26, 2002, following the attacks of September 11, 2001, to address disruptions in the market for terrorism risk insurance, to help ensure the continued availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for the private markets to stabilize and build insurance capacity to absorb any future losses for terrorism events. TRIA requires insurers to ''make available'' terrorism risk insurance for commercial property and casualty losses resulting from certified acts of terrorism (insured losses), and provides for shared public and private compensation for such insured losses. The Secretary of the Treasury (Secretary) administers the Program, including the issuance of regulations and procedures. Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Federal Insurance Office assists the Secretary in administering the Program.[2]

The Program has been reauthorized three times.[3] Most recently, on January 12, 2015, the President signed into law the Terrorism Risk Insurance Program Reauthorization Act of 2015 (2015 Reauthorization Act),[4] reauthorizing the Program until December 31, 2020. The 2015 Reauthorization Act changed various operational matters respecting the Program. Among other changes, the 2015 Reauthorization Act mandates that Treasury issue final rules governing the certification process,[5] following the submission of a mandated report on improving the process.[6]

II. Previous Rulemaking

To date, rules establishing general provisions implementing the Program, including key definitions, and requirements for policy disclosures and mandatory availability, are found in subparts A, B, and C of 31 CFR part 50.[7] Treasury's rules applying provisions of the Act to state residual market insurance entities and state workers' compensation funds are set forth in subpart D of 31 CFR part 50.[8] Rules concerning claims procedures governing payment of the Federal share of compensation for insured losses are currently found at subpart F of 31 CFR part 50.[9] Subpart G of 31 CFR part 50 currently contains rules on audit and recordkeeping requirements for insurers,[10] while subpart H of 31 CFR part 50 currently addresses recoupment and surcharge procedures.[11] Finally, subpart I of 31 CFR part 50 currently contains rules implementing the litigation management provisions of

[1] Public Law 107–297, 116 Stat. 2322, codified at 15 U.S.C. 6701, note. Because the provisions of TRIA (as amended) appear in a note, instead of particular sections, of the United States Code, the provisions of TRIA are identified by the sections of the law.

[2] 31 U.S.C. 313(c)(1)(D).

[3] Terrorism Risk Insurance Extension Act of 2005, Public Law 109–444, 119 Stat. 2660; Terrorism Risk Insurance Program Reauthorization Act of 2007, Public Law 110–160, 121 Stat. 1839; Terrorism Risk Insurance Program Reauthorization Act of 2015, Public Law 114–1, 129 Stat. 3.

[4] Public Law 114–1, 129 Stat. 3.

[5] TRIA, section 102(1)(D).

[6] 2015 Reauthorization Act, section 107. *See* U.S. Department of the Treasury, *The Process for Certifying an ''Act of Terrorism'' under the Terrorism Risk Insurance Act of 2002* (October 2015) (Certification Report), *available at http://www.treasury.gov/initiatives/fio/reports-and-notices/Documents/2015%20Report%20on%20the%20Certification%20Process%20under%20the%20Terrorism%20-%20Production%20Version.pdf.*

[7] *See* 68 FR 9804 (Feb. 28, 2003) (Program definitions (Interim Final Rule)); 68 FR 19302 (April 18, 2003) (disclosure and mandatory availability requirements (Interim Final Rule)); 68 FR 41250 (July 11, 2003) (Program definitions (Final Rule)); 68 FR 48280 (Aug. 13, 2003) (''direct earned premium'' definition (Final Rule)).

[8] *See* 68 FR 19309 (Apr. 18, 2003) (residual market entities and state compensation funds (Notice of Proposed Rulemaking)); 68 FR 59715 (Oct. 17, 2003) (residual market entities and state compensation funds (Final Rule)).

[9] *See* 68 FR 67100 (Dec. 1, 2003) (claims procedures (Notice of Proposed Rulemaking)); 69 FR 39296 (June 29, 2004) (claims procedures (Final Rule)); 70 FR 2830 (Jan. 18, 2005 (timing of affiliation for purposes of claims payments (Notice of Proposed Rulemaking)); 70 FR 34348 (June 14, 2005) (timing of affiliation for purposes of claims payments (Final Rule)).

[10] *See* 68 FR 67100 (Dec. 1, 2003) (audit and investigative procedures (Notice of Proposed Rulemaking)); 69 FR 39296 (audit and investigative procedures (Final Rule)).

[11] *See* 73 FR 53798 (Sept. 17, 2008) (recoupment and surcharge procedures (Notice of Proposed Rulemaking)); 74 FR 66051 (Dec. 14, 2009) (recoupment and surcharge procedures (Final Rule)).

TRIA,[12] and subpart J of 31 CFR part 50 currently addresses rules concerning the cap on annual liability established under TRIA.[13] To assist insurers, policyholders, and other interested parties in complying with immediately applicable requirements of the Act, Treasury has also at times issued interim guidance to be relied upon by insurers until superseded by regulations.

No rules concerning the certification process have previously been proposed or issued by Treasury.[14]

III. The Proposed Rule

The proposed rule on which this interim final rule is based was published in the **Federal Register** at 81 FR 18950 on April 1, 2016. The proposed rule included Subpart G—Certification to 31 CFR part 50, which comprises regulations addressing the certification process, as required under the 2015 Reauthorization Act. Proposed subpart G, which is new, is part of a general proposal published on April 1, 2016 to strike existing 31 CFR part 50 in its entirety and to replace it with revised Program rules that incorporate new financial and operational provisions for the Program added in the 2015 Reauthorization Act. The proposal also reorders the existing rules to incorporate the new subparts, and makes other changes to further clarify existing rules and to eliminate redundancies.

Pursuant to the 2015 Reauthorization Act, Treasury submitted a report to Congress in October 2015 entitled *The Process for Certifying an ''Act of Terrorism'' under the Terrorism Risk Insurance Act of 2002* (Certification Report). The proposed rules concerning the certification process are consistent with Treasury's findings in the Certification Report. For example, Treasury determined that a rule governing the certification process that required the Secretary to render a certification decision within a given time following an act could adversely affect the Secretary's ability to collect information necessary to that decision.[15] Furthermore, the 2015 Reauthorization Act specifically requires the establishment of a timeline for which an act is *eligible* for certification. Treasury's proposed rules identified the required timing considerations as to when an act is eligible for certification and Treasury believes that additional issues concerning milestones and certainty respecting the certification process are best addressed by procedures providing for improved notification and communication to the public once an act is under review for certification. Treasury's observation in 2003 concerning how an ''act of terrorism'' may occur in various and unpredictable ways, that render imposition of a timeline subject to rigid deadlines impracticable, remains true today as well:

> [T]here is no way to predict future events and ascertain a time frame that would be appropriate for all potential situations. Facts could be immediately available and, after consultation, present a clear basis for a quick determination by the Secretary; conversely, a determination could require more time to gather information and conduct an analysis of the act.[16]

IV. Summary of Comments and Interim Final Rule

Treasury is now issuing this interim final rule concerning the certification process after careful consideration of all comments received on the proposed rule. While this interim final rule largely reflects the proposed rule, Treasury has made several revisions based on the comments received, and Treasury solicits comment on the changes to the timeline for eligibility for certification adopted in this interim final rule. Treasury expects to issue final rules based on this interim final rule and the rules proposed in the Notice of Proposed Rulemaking published on April 1, 2016 in the near future.

Ten commenters responded to the proposed rule concerning the certification process. The ten commenters included insurance industry trade associations; a trade association representing consumers of terrorism risk insurance; an insurance company; Lloyd's (an insurance and reinsurance market); a captive insurance manager; and an individual.[17] The comments received and Treasury's revisions to the proposed rule are summarized below.

1. Certification (§ 50.60)

Proposed § 50.60 sets forth the general parameters of the certification process, as required under TRIA, as amended by the 2015 Reauthorization Act. It establishes in paragraph (b) that, from a timing standpoint, an act which satisfies the definition of an act of terrorism is eligible for certification once the Secretary has consulted with the Attorney General of the United States and the Secretary of Homeland Security, in accordance with the requirements of the Reauthorization Act. Most of the comments received by Treasury concerning the certification process involve this provision. One comment states that the proposed rule ''falls short of what was required by Congress'' with respect to the certification process because there is no ''clear timeline for certification decisions.''[18] Other comments also provide suggestions for specific deadlines to be imposed upon the certification decision, although the other commenters do not imply that such a specific timeline is a statutory requirement.[19]

The 2015 Reauthorization Act, at Section 107(e), requires only that a final rule concerning the certification process include ''a timeline for which an act is eligible for certification by the Secretary on whether an act is an act of terrorism under this paragraph.'' This means that Section 107(e) requires that Treasury promulgate rules establishing a timeline for when an act is *eligible* for certification as an act of terrorism,

[12] *See* 69 FR 25341 (May 6, 2004) (Federal cause of action and settlement approval provisions (Notice of Proposed Rulemaking)); 69 FR 44932 (July 28, 2004) (Federal cause of action and settlement approval provisions (Final Rule)).

[13] *See* 73 FR 56767 (Sept. 30, 2008) (cap on annual liability (Notice of Proposed Rulemaking)); 74 FR 66061 (Dec. 14, 2009) (cap on annual liability (Final Rule)).

[14] Although, and as noted below, Treasury has previously responded to comments provided in response to proposed rules concerning applicable definitional provisions for the Program that Treasury ''establish a time frame within which the Secretary would be required to make a determination or certification that an 'act of terrorism' had occurred. . . .'' *See* 68 FR 41250, 41252 (July 11, 2003).

[15] Certification Report at 9.

[16] 68 FR 41250, 41252 (July 11, 2003).

[17] Comments addressing the certification process in some fashion were submitted by the American Insurance Association (AIA Comments); The Council of Insurance Agents & Brokers (CIAB Comments); the National Association of Mutual Insurance Companies (NAMIC Comments); the Property Casualty Insurers Association of America (PCIAA Comments); the Reinsurance Association of America (RAA Comments); The Coalition to Insure Against Terrorism (CIAT Comments); Exchange Indemnity Company (Exchange Indemnity Comments); Lloyd's of London (Lloyd's Comments); Marsh Captive Solutions (Marsh Captive Solutions Comments); and Jason M. Schupp (Jason Schupp Comments). All of the comments received in connection with the proposed rules published for comment on April 1, 2016, are *available at https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=TREAS-TRIP-2016-0005.*

[18] CIAT Comments at 2.

[19] PCIAA Comments at 4–5 (incorporating prior comment filed in connection with Treasury's preparation of the Certification Report, at 2) (preliminary certification decision within 15 days following the potential act of terrorism, and a final decision 60 days after the potential act of terrorism); CIAB Comments at 2 (proposing certification timeframe of 90 days); CIAT Comments at 2 (proposing as an ''appropriate limit'' 45 days after Treasury commences review of an act, or receives a request from either an insurer or policyholder that it commence such review).

rather than for when that act will be certified.

The 2015 Reauthorization Act also does not include any requirements for including specific deadlines in the eligibility timeline. Indeed, the previously proposed version of the 2015 Reauthorization Act did contain such specific deadline requirements, *see* H. Rept. 113–523, 45, but the final version passed by Congress instead delegated authority to establish a timeline to Treasury. Furthermore, Congress required Treasury to conduct a study on the establishment of a reasonable timeline by which the Secretary must make an accurate determination on whether to certify an act before issuing this rule. This sequence provides evidence that Congress intended for Treasury to adopt rules governing the certification process that reflect the findings of the study. The Senate Banking Committee report reflects this intent, noting that ''[a]fter the conduction of the study, the Secretary would be required to issue regulations under existing authorities governing the certification process to address the finding of the study.'' S. Rept. 113–199, 9. Based on the statutory text and legislative history, Treasury believes that it is not required to adopt a timeline that includes a strict deadline for certification.

Treasury also believes that it would not be prudent to adopt such a timeline that includes such strict deadlines. The principal problems the study identified with imposing a time by which an act must be certified are two-fold. First, certification may implicate complex issues relating to the motivation of the actor(s) involved in a particular situation or the actual facts of the situation, all of which may be subject to ongoing criminal investigations (of unknown duration), and Treasury may need to await the results of such investigations before determining whether to certify an act of terrorism.[20] For example, the Secretary may not be able to determine whether an airplane crashing in the ocean is an act of terrorism or a mechanical failure until the black box is recovered. Such recovery may take several months or years. A rule requiring that a certification decision be made within any specified time period keyed to the occurrence of an act could force the Secretary to make a decision without all of the relevant information. Accordingly, it is important that the Secretary's decision be made only after considering all of the relevant information. Given the wide differences in circumstances surrounding potential acts of terrorism, Treasury does not believe that it would be reasonable to establish any specific deadlines for certification, even where such deadlines could be extended when necessary.

The second problem identified in the report is that, in many cases, insurance losses may take substantial periods of time to develop before Treasury can determine whether an act is even eligible for certification.[21] For example, it could take years to fully evaluate whether insurance losses related to certain events (*e.g.,* the introduction of a carcinogenic agent into a municipal water supply) result in losses above the certification threshold. No commenters have suggested that these issues are illusory, or offered for consideration any mechanisms to avoid the problems that a timeline subject to specific deadlines presents given these realities.

The renewed calls for a timeline subject to precise deadlines have also been based upon arguments that insurers require a quick decision respecting certification of an act of terrorism because of the effect that this determination might have upon coverage issues, and their obligations to respond promptly to claims under state law provisions.[22] In addition, some commenters have suggested that a certification decision made within a defined time is necessary for economic stability and for a proper functioning insurance market.[23]

Although Treasury appreciates insurers have obligations to respond to claims in a timely fashion, the state law obligations that have been invoked are subject to extensions when a greater period of time is necessary to make a claims determination.[24] None of the commenters that have invoked these obligations have addressed this feature of state law. Commenters also claimed that a rule with specific deadlines may further ''economic stability'' and avoid ''market consequences,'' yet the commenters did not identify any specific economic or insurance marketplace stability issue resulting from uncertainty about Treasury's position with respect to a particular act. Furthermore, Treasury's public communications under proposed § 50.61 should provide sufficient information to allow market participants to take appropriate steps pending the finalization of a future certification process.

While Treasury believes, based on the statutory text and the findings in the Certification Report, that adopting strict deadlines is neither required by statute nor an appropriate policy decision, the regulations as adopted in this interim final rule have been modified to more clearly lay out a timeline for whether an act is eligible for certification by the Secretary as an act of terrorism. Each of the events outlined in this interim final rule were contemplated in the proposed rule, but are now consolidated in a single schedule to provide for greater clarity. The timeline in this interim final rule clarifies that there will be (1) a commencement to this process, subject to public notification, as discussed in proposed § 50.61(a); (2) regular public notification under the schedule set forth in proposed § 50.61(b); (3) a period of time during which the Secretary evaluates the factors relevant to the certification decision, which is subject to regular public notification of continued review, as reflected in proposed § 50.61(b); and (4) a consultation between the Secretary and the Attorney General and Secretary of Homeland Security, as required by TRIA, as reflected in proposed § 50.60(a), (b). Because the consultation required by TRIA will take place after the Secretary has obtained relevant information and completed the review identified in Step 3, the concerns militating against adoption of specific deadlines do not apply to the timing of the consultation. Therefore, Treasury can and has identified a time period of 30 days during which this action can be expected to occur. Treasury specifically

[20] Certification Report at 9 (''In order for the Secretary to make an informed certification decision in accordance with the statutory criteria, for example, Treasury might need to coordinate with other government agencies conducting investigations concerning the perpetrators of or motivations for the act. The Secretary will also need to be respectful of activities of law enforcement and the justice system concerning the investigation, apprehension, and prosecution of the individual or individuals suspected or accused of committing the act.'' (Footnote omitted.)).

[21] Certification Report at 9–10 (''Loss development patterns—*i.e.,* the severity, timing, and distribution of losses as information becomes available—are not always predictable from preliminary information and will be affected by the magnitude and type of act under consideration for certification. The time it may take for claims to be submitted to one or more insurers by affected policyholders after an act has occurred, for those claims to be investigated and adjusted by the insurers, and (if appropriate) to be reserved or paid by the insurers, might vary considerably.'').

[22] Lloyd's Comments at 1–2; PCIAA Comments at 4–5 (incorporating prior comments at 1).

[23] CIAB Comments at 2; CIAT Comments at 2.

[24] Certification Report at 8 n.36 (observing that state model regulations identified by insurers as imposing time deadlines upon claims decisions, which have been adopted in some form by 47 states and two territories, provide ''the opportunity to obtain further time, upon notice to the policyholder, within which to make the claims determination'') (citing NAIC, Unfair Property/Casualty Claims Settlement Practices Model Regulation, 902–4, section 7.B, *available at http://www.naic.org/store/free/MDL-902.pdf*).

solicits comment on whether there are any reasonable improvements to the timeline set forth in this interim final rule that would provide further clarity concerning the process, in a way that would materially benefit interested parties and which would still be practical given the nature of the process and the issues with a strict deadline identified by Treasury.

Two commenters suggested the inclusion of a provision that would permit an interested party (identified as either an insurer or a policyholder) to request that Treasury make a certification determination regarding a particular act.[25] Another commenter proposed a ''dispute resolution and/or notice and comment procedure to ensure that all impacted parties are given the opportunity to address concerns surrounding certification or non-certification of an event.'' [26] Such comments fail to appreciate the nature of the certification determination entrusted to the Secretary under TRIA.

Initially, the certification decision is entrusted to the Secretary, who is empowered with non-delegable authority under TRIA to determine whether to certify an act as an act of terrorism, once there has been the required consultation between the Secretary, the Attorney General, and the Secretary of Homeland Security. TRIA recognizes the high levels of sensitivity embodied in this determination by making this decision final and not subject to judicial review. The Secretary, in consultation with the Attorney General and the Secretary of Homeland Security, may, for instance, conclude that law enforcement priorities require waiting to make the certification decision. Permitting an insurer or policyholder to trigger a certification determination, or to be able to dispute the certification or non-certification of an event would be inconsistent with TRIA's delegation of authority to the Secretary to make the determination on a non-reviewable basis. Moreover, nothing in TRIA or Treasury's proposed rules prohibits a stakeholder from contacting Treasury to bring to its attention an event that the stakeholder believes might be subject to certification under TRIA, or other information relevant to that event. Treasury's adoption of proposed § 50.62(b) specifically recognizes the value that stakeholder input has to the certification process. Furthermore, a dispute resolution or notice and comment procedure would only operate to delay a certification determination, which is inconsistent with comments otherwise offered that a timeline is necessary to insure that a timely certification decision is made.

Two additional comments concerning proposed § 50.60 warrant attention. First, two commenters note that proposed § 50.60(a), as currently proposed, could be read to require that the Secretary consult with the Attorney General and the Secretary of Homeland Security even when ultimately deciding not to certify an act as an act of terrorism.[27] It was not Treasury's intent to impose a consultation requirement where the Secretary determines not to certify, and in this context the word ''whether'' in proposed § 50.60(a) should not be read to impose any obligation on the Secretary that would be inconsistent with the Secretary's discretion under TRIA. Accordingly, this interim final rule adopts § 50.60(a) as originally proposed, subject to this understanding.

Second, another comment observes that there is circularity in the provisions of proposed § 50.60(b), respecting the timing of when a certification decision can take place, in that the cross-reference in proposed § 50.60(b) to proposed § 50.4(b) (the ''act of terrorism'' definition) incorporates the consultation process which then would have to take place before the consultation process identified in proposed § 50.60(b). Thus, the commenter observes, proposed § 50.60(b) could be read to suggest ''that no act could ever be certified because only previously certified acts are eligible for certification,'' and that the provision should just be deleted.[28]

Proposed § 50.60(b) cannot be eliminated, as it is a necessary provision setting forth the timeline for when an act is eligible for certification by the Secretary as an act of terrorism. Treasury's modification of proposed § 50.60(b) to better reflect the timeline contemplated in the proposed rule resolves this ambiguity. As noted, this formulation is already contemplated by the proposed rules, and as expressed in this fashion provides for a clearer ordering of the relevant milestones that avoids the potential circularity issue identified in the comments.

For the reasons set forth above, Treasury will modify proposed § 50.60 as described above, and adopt in this interim final rule § 50.100 as so amended. As noted at the outset, this section of the interim final rule is for now adopted as § 50.100 to avoid duplication with existing rule numbers, and we anticipate it will be renumbered to § 50.60 in the final rule.

2. Public Communication (§ 50.61)

Proposed § 50.61 addresses the commencement of the certification process and public communication concerning the process. As Treasury explained in the Certification Report, public communication respecting the certification process provides the public with necessary information concerning the certification process in a way that is not subject to the problems inherent with a strict timeline, as addressed above.[29] No commenters disagreed with Treasury's proposal to provide such public communication of the certification process. Three commenters suggested that the proposed rule should incorporate a deadline or milestones to govern when Treasury must notify the public that an act is being considered for certification, and even to provide ''preliminary indications'' respecting certification at that point of initial notification.[30] One commenter suggested a change to proposed § 50.61(a) to confirm that Treasury will only provide public notification where an act is actually under review for certification as an act of terrorism, ''to avoid any suggestion [Treasury's] routine monitoring of events should trigger expectations of public notification.'' [31]

In response to the comments, Treasury has modified proposed § 50.61(a) to provide that once the Secretary commences review, Treasury shall publish a document in the **Federal Register** within 30 days notifying the public of this fact. Although this provision remains subject to the rule of construction that would permit the modification of this date by the Secretary in the event that timely notification is impracticable, the modification to the proposed rule reflects Treasury's intention to provide notification of the commencement of a certification process within 30 days.

As respects the comment that a revision to proposed § 50.61(a) may be in order to confirm that public notification should not be expected simply on account of the ''routine monitoring of events'' by Treasury, the proposed rule should not engender any such expectations. Notice will be

[25] Lloyd's Comments at 2; CIAT Comments at 2.

[26] CIAB Comment at 3.

[27] Jason Schupp Comments at 8; AIA Comments at 7.

[28] Jason Schupp Comments at 8–9.

[29] Certification Report at 10–11.

[30] Lloyd's Comments at 2; CIAT Comments at 2; *see* NAMIC Comments at 4 (initial notification that certification is under review ''should also contain a preliminary indication as to whether Treasury expects that the act will be certified as an act of terrorism'').

[31] Jason Schupp Comments at 9.

provided when the Secretary determines that an act should be considered for certification as an act of terrorism under TRIA. Nothing in the proposed rule suggests, or is meant to suggest, that consideration of current events by Treasury short of the Secretary's determination to commence the certification process will trigger any sort of public notification by Treasury.

For the above reasons, Treasury will modify proposed § 50.61 as described above, and adopt in this interim final rule § 50.101 as so amended. As noted at the outset, this section of the interim final rule is for now adopted as § 50.101 to avoid duplication with existing rule numbers, and we anticipate it will be renumbered to § 50.61 in the final rule.

3. Certification Data Collection (§ 50.62)

A few comments were received concerning proposed § 50.62, which establishes rules for the collection of data by Treasury in aid of the certification process. Under TRIA, the Secretary may not certify an act as an act of terrorism unless property and casualty insurance losses resulting from the act, in the aggregate, exceed $5 million. Treasury may need to collect data from insurers, as well as from other entities in the insurance industry, in connection with its analysis of whether the insurance losses resulting from an act under review for certification satisfy the loss threshold.

No comments were received asserting that the proposed rule was unnecessary.[32] Two comments suggested that some restrictions upon the data collection provision should be incorporated, to allow insurers to challenge a request on the grounds that an insufficient period to respond has been provided, or that the request is unduly broad, burdensome, or involves confidential information.[33] Because these requests involve the certification process, Treasury may need to obtain information on an accelerated basis. However, in setting the reporting deadline, Treasury will take into account the amount and the complexity of the information requested. Regarding the scope of any requests, the act under review will define the scope of the needed information, and Treasury expects that any requests will be narrowly tailored to the act in question which should prevent any requests from being unduly broad or burdensome. As respects confidentiality, proposed § 50.54 (concerning Handling of Data) already sufficiently addresses the treatment of any confidential information that might be obtained pursuant to proposed § 50.62. Accordingly, no changes to proposed § 50.62 for the reasons identified are warranted.

Another comment observed that any certification data collection process should be ''a streamlined, orderly method for collecting and organizing data from carriers and their affiliates, as well as a federal consolidation point for claims data (perhaps FIO),'' and encourages that any final rules ''include a centralized data collection process for purposes of the certification determination.'' [34] No specific language or revisions to achieve this goal, however, were suggested.

Although Treasury is in agreement with the sentiments of this comment, proposed § 50.62 sets forth the sort of process identified by the commenter. The certification process is one that is solely within the responsibility of the Secretary, who is assisted by FIO in the administration of the Program. Proposed § 50.62 sets forth a process under which Treasury will collect insurance-related information relevant to the certification decision, and does not contemplate that this will be accomplished through any other federal agencies or processes. While requests are likely to be tailored to address a particular situation, such that different requests may be made from case to case, nothing in the rule contemplates any sort of process that would subject responding entities to conflicting, disparate requests for information.

For the above reasons, Treasury is adopting § 50.102 as it was proposed. As noted at the outset, this section of the interim final rule is for now adopted as § 50.102 to avoid duplication with existing rule numbers, and we anticipate it will be renumbered to § 50.62 in the final rule.

4. Notification of Certification Determination (§ 50.63)

Proposed § 50.63 provides for **Federal Register** notification and other communication of any certification decision, as well as separate notifications to Congress and specified insurance supervisory authorities. One commenter observed that proposed § 50.63 should only require notification of ''actual certification decisions,'' and not for ''acts that clearly will not meet the definition outlined in TRIA.'' [35] Another commenter suggested that the rule could be modified to provide that notice under proposed § 50.63 will be provided only for those situations where Treasury has provided notice under proposed § 50.61(a) that an act is under review for certification as an act of terrorism.[36]

Treasury acknowledges that it monitors events and situations that, given their circumstances, could potentially involve the Program. The proposed certification rules address and contemplate situations in which the Secretary (1) determines that an act will or will not be certified as an act of terrorism without any prior advance notification to the public (see proposed § 50.61(d), as adopted below); or (2) commences review of whether to certify an act as an act of terrorism, as provided for in proposed § 50.61(a). The notification procedures under proposed § 50.63 govern these situations, once a decision whether to certify has been made by the Secretary.

For the above reasons, Treasury is adopting § 50.63 as it was proposed. As noted at the outset, this section of the interim final rule is for now adopted as § 50.103 to avoid duplication with existing rule numbers, and we anticipate it will be renumbered to § 50.63 in the final rule.

V. Procedural Requirements

Executive Order 12866, ''*Regulatory Planning and Review.*'' Executive Order 12866, as supplemented by Executive Order 13563, establishes a program to reform and make more efficient the regulatory process of the Federal Government. In accordance with such Executive Orders, this rule is a significant regulatory action, and has been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act. In general, the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), which applies to any rule subject to notice and comment rulemaking under the Administrative Procedure Act or any other law, requires a federal agency to conduct a full regulatory flexibility analysis unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. (5 U.S.C. 605(b)). In the preamble to the proposed rule, Treasury certified that the rule, if promulgated, would not have

[32] One comment did take the opportunity to criticize the statutory greater than $5 million aggregate loss threshold aspect of the ''act of terrorism'' definition, asserting that ''the threshold has been more of an impediment to practical application of TRIA than a worthwhile definitional component,'' and observed that ''[a] more useful way of looking at the threshold would be to view it in the context of the TRIA aggregate loss program trigger.'' AIA Comment at 7. Treasury notes that this threshold is prescribed by statute and may not be modified via regulation.

[33] Exchange Indemnity Comments at 2; Marsh Captive Solutions Comments at 2.

[34] CIAB Comments at 3.

[35] AIA Comment at 8.

[36] Jason Schupp Comments at 9.

a significant economic impact on a substantial number of small entities. Treasury did not receive any comments in response to Subpart G of the proposed rule on the impact to small entities or insurers, and the interim final rule has not been revised in any way that warrants a change to this certification. As discussed in the preamble to the proposed rule, some small entities—as defined by the regulations of the SBA (see 13 CFR 121. 201)—and small insurers—as defined by the proposed rules—will be impacted by the rule, but the costs that may be incurred arise from requirements in TRIA and not Treasury regulations.

Paperwork Reduction Act. The proposed collection of information concerning the certification process as contained in the proposed rule was submitted to the Office of Management and Budget (OMB) for review under the requirements of the Paperwork Reduction Act, 44 U.S.C. 3507(d). Although solicited, Treasury did not receive any comments from the public concerning (1) the necessity of the collection of information in aid of the certification process; (2) the accuracy of Treasury's burden estimates; (3) suggestions for enhancement of the quality, utility, and clarity of the information collection; (4) suggestions for minimization of the burden of the information collection; [37] or (5) estimates of capital or start-up costs that would be necessary for compliance with the information collection. The interim final rule does not contain any new collections of information. Under the Paperwork Reduction Act, 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. Treasury will obtain final OMB approval for the collection of information in aid of the certification process prior to any collection of such information.

Administrative Procedure Act. The Administrative Procedure Act (5 U.S.C. 551 *et seq.*) (APA) generally requires public notice before promulgation of regulations. See 5 U.S.C. 553(b). The Department published a notice of proposed rulemaking requesting comment on the proposed rule on April 1, 2016 (81 FR 18949). The Department has considered the comments received in developing this interim final rule but also wishes to provide the public another opportunity to comment on the provisions described in this document.

List of Subjects in 31 CFR Part 50

Insurance, Terrorism.

Authority and Issuance

For the reasons stated in the preamble, 31 CFR part 50 is amended as follows:

PART 50—TERRORISM RISK INSURANCE PROGRAM

■ 1. The authority citation for part 50 is revised to read as follows:

Authority: 5 U.S.C. 301; 31 U.S.C. 321; Title I, Pub. L. 107–297, 116 Stat. 2322, as amended by Pub. L. 109–144, 119 Stat. 2660, Pub. L. 110–160, 121 Stat. 1839 and Pub. L. 114–1, 129 Stat. 3 (15 U.S.C. 6701 note).

■ 2. Subpart K is added to read as follows:

Subpart K—Certification

Sec.
50.100 Certification.
50.101 Public communication.
50.102 Certification data collection.
50.103 Notification of certification determination.

Subpart K—Certification

§ 50.100 Certification.

(a) *Certification decision.* The Secretary, in consultation with the Attorney General of the United States and the Secretary of Homeland Security, is responsible for determining whether to certify an act as an act of terrorism.

(b) *Timeline for eligibility.* An act is eligible for certification as an act of terrorism at the end of the following timeline:

(1) The Secretary commences review of whether an act satisfies the definition in § 50.5(b);

(2) Within 30 days of the Secretary commencing review, Treasury publishes the notice required by § 50.101(a). During such review, the schedule of public notifications in § 50.101(b) shall apply, as appropriate;

(3) The Secretary's review finds that the act satisfies the elements for certification under § 50.5(b)(1)(i) through (iv), and that it is not otherwise precluded from certification by § 50.5(b)(2); and

(4) Within 30 days or as soon as otherwise practicable after the review identified in paragraph (b)(3) of this section concludes that the act satisfies the necessary criteria, the Secretary consults with the Attorney General of the United States and the Secretary of Homeland Security pursuant to section 102(1)(A) of the Act.

(c) *Other consultation.* Nothing in this section shall prevent the Secretary from consulting and coordinating with the Attorney General of the United States, the Secretary of Homeland Security, or any other government official prior to the consultation identified in paragraph (b)(4) of this section.

(d) *Finality.* Any decision by the Secretary to certify, or determination not to certify, an act as an act of terrorism under this Subpart shall be final, and shall not be subject to judicial review.

(e) *Nondelegation.* The Secretary may not delegate or designate to any other officer, employee, or person, the determination of whether to certify an act as an act of terrorism.

§ 50.101 Public communication.

(a) *Initial notification.* After the Secretary commences review of whether an act may satisfy the definition in § 50.5(b), Treasury shall publish a notice in the **Federal Register** within 30 days of the Secretary commencing review notifying the public that the act is under review for certification as an act of terrorism. Treasury may also announce that an act is not under review for certification.

(b) *Update notification.* Not later than 30 days following the publication of a notice under paragraph (a) of this section that an act is under review for certification, and not later than every 60 days thereafter until the Secretary determines whether to certify an act as an act of terrorism, Treasury shall publish a notice in the **Federal Register** notifying the public whether the act is still under review for certification as an act of terrorism.

(c) *Contents of notification.* Nothing in this section shall require Treasury to provide any information other than whether the act is under review for certification as an act of terrorism (or is no longer under such review) or shall limit Treasury from providing further information of relevance.

(d) *Rules of construction.* Nothing in this section shall be construed to preclude the Secretary from certifying or determining not to certify an act as an

[37] As noted above, Treasury did receive one comment suggesting that any certification data collection process should be established to provide for ''a streamlined, orderly method for collecting and organizing data from carriers and their affiliates, as well as a federal consolidation point for claims data (perhaps FIO),'' and encourages that any final rules ''include a centralized data collection process for purposes of the certification determination.'' CIAB Comments at 3. As explained above, Treasury believes that the proposed collection of information, which will be managed through the Federal Insurance Office at Treasury, satisfies the concern identified in this comment. In addition, Treasury also received two comments suggesting the adoption of procedures allowing for various challenges to data as requested by Treasury; however, as explained above, the timing and scope of data required by Treasury will be driven by the nature of the act under review for certification, such that changes to the proposed collection would not be warranted.

act of terrorism before notifying the public that the act is under review for certification. If, in the discretion of the Secretary, circumstances relating to an act render timely notification under this section by Treasury impracticable, Treasury shall provide the notification as soon as practicable, in a manner the Secretary determines is appropriate.

(e) *Nonbinding decision.* A notification made under this section shall not be construed to be a final determination by the Secretary of whether to certify an act as an act of terrorism.

§ 50.102 Certification data collection.

(a) *General.* (1) The Secretary, when reviewing an act for certification as an act of terrorism, may at any time direct one or more insurers to submit information regarding projected and actual losses in connection with an act and any other information the Secretary determines appropriate. The information sought by the Secretary shall be specified in the data request, and any insurer subject to the data request shall respond to the request within the time frame specified by the Secretary at the time of the request. The data requested may include actual loss reserves established by insurers in connection with the act under review, loss estimates generated by insurers in connection with the act under review which have not yet been established as actual loss reserves, and information respecting an insurer's property and casualty exposures in a particular geographic area associated with the act under review.

(2) An insurer not required by Treasury to submit information under paragraph (a)(1) of this section may voluntarily submit information to the Secretary as specified in public notifications issued by Treasury.

(b) *Other sources of information.* The Secretary may request information with respect to loss estimates and likely affected insurers from organizations, including state insurance regulators, insurance modeling organizations, rating agencies, insurance brokers and producers, and insurance data aggregators.

§ 50.103 Notification of certification determination.

(a) *Public notification.* Not later than 5 business days after the Secretary determines whether to certify an act as an act of terrorism, Treasury shall publish a statement and submit a notice to the **Federal Register** notifying the public of the Secretary's decision.

(b) *Insurance supervisor notification.* Not later than 5 business days after the Secretary determines whether to certify an act as an act of terrorism, Treasury shall notify in writing any relevant supervisory officials of the Secretary's decision.

(c) *Congressional notification.* Not later than 5 business days after the Secretary determines whether to certify an act as an act of terrorism, Treasury shall notify in writing the President of the U.S. Senate and the Speaker of the U.S. House of Representatives of the Secretary's decision.

(d) *Rule of construction.* If, in the discretion of the Secretary, circumstances relating to an act render timely notification by Treasury under this section impracticable, Treasury shall provide the notification as soon as practicable, in a manner the Secretary determines is appropriate.

Dated: December 1, 2016.

Amias Moore Gerety,

Acting Assistant Secretary for Financial Institutions.

[FR Doc. 2016–29313 Filed 12–6–16; 8:45 am]

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FEDERAL REGISTER

Vol. 81 Wednesday,

No. 235 December 7, 2016

Part VIII

Department of the Treasury

31 CFR Part 50

Terrorism Risk Insurance Program; Adjustment to Civil Penalty Amount Under the Terrorism Risk Insurance Act of 2002; Interim Final Rule

DEPARTMENT OF THE TREASURY

31 CFR Part 50

Terrorism Risk Insurance Program; Adjustment to Civil Penalty Amount Under the Terrorism Risk Insurance Act of 2002

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Interim final rule.

SUMMARY: The Department of the Treasury (Treasury) is amending its regulations to adjust the civil penalty amount provided for under the Terrorism Risk Insurance Act of 2002 (TRIA). This action, including the amount of the adjustment, is required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: *Effective date:* December 7, 2016. *Comment date:* Written comments may be submitted on or before January 6, 2017. Early submissions are encouraged.

ADDRESSES: Submit comments electronically through the Federal eRulemaking Portal: *http://www.regulations.gov,* or by mail (if hard copy, preferably an original and two copies) to the Federal Insurance Office, Attention: Richard Ifft, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. Because postal mail may be subject to processing delay, it is recommended that comments be submitted electronically. All comments should be captioned with ''Terrorism Risk Insurance Program Civil Penalty Adjustment Comments.'' Please include your name, group affiliation, address, email address and telephone number(s) in your comment. Where appropriate, a comment should include a short Executive Summary (no more than five single-spaced pages).

In general, comments received will be posted on *http://www.regulations.gov* without change, including any business or personal information provided. Comments received, including attachments and other supporting materials, will be part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–2922 (not a toll free number) or Kevin Meehan, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, 202–622–7009 (not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Legal Background

TRIA [1] requires insurers to ''make available'' terrorism risk insurance for commercial property and casualty losses resulting from certified acts of terrorism (insured losses), and provides for shared public and private compensation for such insured losses through the Terrorism Risk Insurance Program (TRIP or Program). The Secretary of the Treasury (Secretary) administers the Program; pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Federal Insurance Office assists the Secretary in administering the Program.

Section 104(e) of TRIA authorizes the Secretary to assess civil penalties for certain violations of statutory and regulatory provisions concerning the administration of the Terrorism Risk Insurance Program and the assertions of claims under the Program by participating insurers. The civil penalty amount under TRIA may not exceed the greater of $1,000,000 or the amount in dispute in the case of any failure to pay, charge, collect, or remit amounts in accordance with requirements of TRIA or its implementing regulations. Treasury recently proposed implementing regulations for this provision for the first time (TRIP Rule).[2] Treasury has never assessed civil penalties under this statute.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 [3] (Improvements Act) amended the inflation adjustment calculation previously required by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (FCPIA Act).[4] The Improvements Act requires that penalty amounts initially be adjusted for inflation pursuant to a catch-up ''cost-of-living adjustment'' through an interim final rulemaking. The Improvements Act also requires subsequent annual adjustments no later than January 15 of each year after 2016.

Section 5(b) of the Improvements Act defines the initial cost-of-living adjustment as ''the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of October 2015 exceeds the Consumer Price Index for the month of October of the calendar year during which the amount of such civil monetary penalty was established or adjusted pursuant to law.'' Section 5(a) requires that any increase be rounded to the nearest multiple of $1.

II. Proposed Rulemaking

In the TRIP Rule, Treasury proposed, among other provisions, adjusting the civil penalties amount based on the formula required by the FCPIA Act before its amendment by the Improvements Act. Adoption of the amount proposed in the TRIP Rule would not comply with the requirements of the Improvement Act. Therefore, when Treasury issues the final TRIP Rule provisions respecting the assessment of civil penalties, the civil penalty amount authorized under Section 104(e) of TRIA will remain the amount reflected in this adjustment.

Because the Improvements Act requires that civil penalty amounts be adjusted by an interim final rulemaking issued no later than July 1, 2016, Treasury is issuing this interim final rule to adjust the existing civil penalty amount under TRIA from $1,000,000 to $1,311,850. This adjustment will take effect upon publication of this interim final rule.

This interim final rule also provides for the annual readjustment of the civil penalty amount under TRIA as required by the Improvements Act. Although currently numbered as 31 CFR 50.86, we anticipate that the provisions contained in this interim final rule will be renumbered as 31 CFR 50.83 and included in any TRIP final rules as ultimately issued, pursuant to Treasury's April 1, 2016 Notice of Proposed Rulemaking.

III. Calculation of Inflation Adjustment

Under the Improvements Act, Treasury is required to adjust the level of the TRIA civil monetary penalty with an initial ''catch up'' adjustment through this interim final rulemaking. The calculation is based upon the percentage by which the Consumer Price Index (CPI–U) for October 2002 (the year the TRIA civil penalty was established) exceeds the October 2015 CPI–U. That calculation results in a multiplier of 1.31185, meaning that the CPI–U from 2015 exceeds the CPI–U from 2002 by 31.185%. Based on the original $1,000,000 civil penalty amount, Treasury is adjusting the current civil penalty amount (with an increase rounded to the nearest dollar, as required by the Improvements Act) to $1,311,850.

[1] 15 U.S.C. 6701 note (Pub. L. 107–297, 116 Stat. 2322). Because the provisions of TRIA (as amended) appear in a note, instead of particular sections, in the United States Code, the provisions of TRIA are identified by the sections of the public law.

[2] Notice of Proposed Rulemaking, 81 FR 18950, 18972 (proposed 50 CFR 50.82) (April 1, 2016).

[3] Public Law 114–74.

[4] 28 U.S.C. 2461 note.

IV. Request for Comments

Treasury invites comments on this notice. Commenters are specifically encouraged to identify any technical issues raised by the rule.

Procedural Requirements

Under the Improvements Act, civil penalties are to be adjusted by interim final rule. Because Treasury must adjust the civil penalties provision of TRIA according to a statutory formula and because the law mandates use of an interim final rule to make the adjustment, Treasury finds that good cause exists to forego publishing a notice of proposed rulemaking and providing opportunity for public comment under the Administrative Procedure Act. 5 U.S.C. 553(b)(3)(B). Because the statute provides for these adjustments to go into effect by August 1, 2016, Treasury finds that good cause exists for this interim final rule to go into effect upon publication. 5 U.S.C. 553(d)(3). Because these adjustments are mandated by statute and do not involve the exercise of Treasury's discretion or any policy judgments, public notice and comment before adopting these amendments as final is unnecessary. Because no general notice of proposed rulemaking is required, the requirements of the Regulatory Flexibility Act [5] do not apply. Finally, this rule does not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995 as amended.[6]

List of Subjects in 31 CFR Part 50

Insurance, Terrorism.

For the reasons stated in the preamble, the Department of the Treasury amends 31 CFR part 50 as follows:

PART 50—TERRORISM RISK INSURANCE PROGRAM

■ 1. The authority citation for part 50 is revised to read as follows:

Authority: 5 U.S.C. 301; 31 U.S.C. 321; Title I, Pub. L. 107–297, 116 Stat. 2322, as amended by Public Law 109–144, 119 Stat. 2660, Pub. L. 110–160, 121 Stat. 1839 and Pub. L. 114–1, 129 Stat. 3 (15 U.S.C. 6701 note); Pub. L. 114–74, 129 Stat. 601, Title VII (28 U.S.C. 2461 note).

Subpart I—Federal Cause of Action; Approval of Settlements

■ 2. Section 50.86 is added to read as follows:

§ 50.86 Adjustment of civil monetary penalty amount.

(a) *Catch-up adjustment.* Any penalty under the Act and these regulations may not exceed the greater of $1,311,850 and, in the case of any failure to pay, charge, collect, or remit amounts in accordance with the Act or these regulations such amount in dispute.

(b) *Annual adjustment.* The maximum penalty amount that may be assessed under this section will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. 2461 note, by January 15 of each year and the updated amount will be posted in the **Federal Register** and on the Treasury Web site at *https://www.treasury.gov/resource-center/fin-mkts/Pages/program.aspx*.

Dated: December 1, 2016.

Amias Moore Gerety,

Acting Assistant Secretary for Financial Institutions.

[FR Doc. 2016–29314 Filed 12–6–16; 8:45 am]

BILLING CODE 4810–25–P

[5] 5 U.S.C. 601 *et seq.*

[6] 44 U.S.C. 3501 *et seq.*

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Part IX

The President

Proclamation 9550—International Day of Persons With Disabilities, 2016

Order of December 2, 2016—Regarding the Proposed Acquisition of a Controlling Interest in Aixtron SE by Grand Chip Investment GmbH

Federal Register
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Presidential Documents

Title 3—

The President

Proclamation 9550 of December 2, 2016

International Day of Persons With Disabilities, 2016

By the President of the United States of America

A Proclamation

Over a quarter-century ago, the United States enshrined into law the principles of equal access and equal opportunity for people with disabilities through the Americans with Disabilities Act (ADA), which upholds the principle that each of us is entitled to a set of fundamental freedoms and protections. This progress has made America a leader in advancing the rights of people with disabilities around the globe. On International Day of Persons with Disabilities, we celebrate how far we have come in protecting the rights of those who live with disabilities and recommit to shaping a future in which all members of this community can enjoy their full rights and freedoms.

Building on the progress of the ADA, my Administration has taken important steps to remove barriers and eliminate discrimination based on disability. Thanks to the Affordable Care Act, individuals can no longer be denied coverage because of a pre-existing condition or disability. We have supported increasing funding for the Individuals with Disabilities Education Act, reauthorized the Children's Health Insurance Program, and strengthened anti-discrimination and Olmstead enforcement at the Department of Justice. Additionally, we created the first-ever Special Advisor for International Disability Rights, and we established the United States Strategy to Prevent and Respond to Gender-Based Violence Globally in order to address violence against women and girls around the world—because women with a disability are more likely to experience physical and sexual abuse than women without one. And last year, we committed to achieving the Sustainable Development Goals, which recognize inclusive education, disability employment, and social acceptance of the disability community as important steps to ending world poverty.

Our progress at home reflects our full commitment to the rights of people with disabilities around the world. America was the first country to comprehensively address non-discrimination on the basis of disability in national legislation and declare that disability rights are human rights which must be recognized and promoted everywhere. In my first year in office, the United States joined 140 other nations in signing the United Nations Convention on the Rights of Persons with Disabilities—the first international human rights convention to fully address human rights in the context of disability. Now joined by over 160 States Parties, this Convention serves as a beacon of hope to the more than 1 billion people worldwide who live with a disability—a reminder that the need to protect disability rights does not end at our borders. Regrettably, the Senate has still not provided its advice and consent for ratification of this Convention, and I urge them to do so and to uphold our global commitment to the international disability community.

We have taken important steps forward to advance the rights of persons with disabilities, but the fight is not over. As long as anyone succumbs to casual discrimination or fear of the unfamiliar, we have more work to do to honor the many people with disabilities who have shared their stories of exclusion and injustice—and the millions more they spoke up

for. Because of the advocates who have led the way, more individuals with disabilities can pursue their full measure of happiness. They have taught us that our world is far better off when all people can live up to their full potential—it makes all of us more whole, and it makes our world a better place.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim December 3, 2016, as International Day of Persons with Disabilities. I call on all Americans to observe this day with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of December, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–29485
Filed 12–6–16; 11:15 am]
Billing code 3295–F7–P

Presidential Documents

Order of December 2, 2016

Regarding the Proposed Acquisition of a Controlling Interest in Aixtron SE by Grand Chip Investment GmbH

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 721 of the Defense Production Act of 1950, as amended (section 721), 50 U.S.C. 4565,

Section 1. *Findings.* I hereby make the following findings:

(a) There is credible evidence that leads me to believe that: (1) Grand Chip Investment GmbH, a limited liability company organized under the laws of the Federal Republic of Germany (Grand Chip); (2) Grand Chip's parent companies Grand Chip Investment S.a.r.l., a company organized under the laws of the Grand Duchy of Luxembourg (GC Investment), and Fujian Grand Chip Investment Fund LP, a limited partnership organized under the laws of the People's Republic of China (Fujian Grand); and (3) Fujian Grand's partners, Mr. Zhendong Liu, a citizen of the People's Republic of China (Mr. Liu), and Xiamen Bohao Investment Co. Ltd., a company organized under the laws of the People's Republic of China (Xiamen Bohao and, together with Grand Chip, GC Investment, Fujian Grand, and Mr. Liu, the Purchasers), through exercising control of the U.S. business of AIXTRON SE., a company organized under the laws of the Federal Republic of Germany (Aixtron), might take action that threatens to impair the national security of the United States. The U.S. business of Aixtron consists of AIXTRON, Inc., a California corporation, the equity interests of AIXTRON, Inc., and any asset of Aixtron or AIXTRON, Inc. used in, or owned for the use in or benefit of, the activities in interstate commerce in the United States of AIXTRON, Inc., including without limitation any interest in any patents issued by, and any interest in any patent applications pending with, the United States Patent and Trademark Office (collectively, Aixtron US); and

(b) Provisions of law, other than section 721 and the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), do not, in my judgment, provide adequate and appropriate authority for me to protect the national security in this matter.

Sec. 2. Actions Ordered and Authorized. On the basis of the findings set forth in section 1 of this order, considering the factors described in subsection 721(f), as appropriate, and pursuant to my authority under applicable law, including section 721, I hereby order that:

(a) The proposed acquisition of Aixtron US by the Purchasers is hereby prohibited, and any substantially equivalent transaction, whether effected directly or indirectly through the Purchasers' shareholders, partners, subsidiaries, or affiliates is prohibited.

(b) In order to effectuate this order, the Purchasers and Aixtron shall take all steps necessary to fully and permanently abandon the proposed acquisition of Aixtron US not later than 30 days after the date of this order, unless such date is extended by the Committee on Foreign Investment in the United States (CFIUS) for a period not to exceed 90 days, on such written conditions as CFIUS may require. Immediately upon completion of all steps necessary to terminate the proposed acquisition of Aixtron US, the Purchasers and Aixtron shall certify in writing to CFIUS that such termination has been effected in accordance with this order and that all steps necessary to fully and permanently abandon the proposed acquisition of Aixtron US have been completed.

(c) From the date of this order until the Purchasers and Aixtron provide a certification of termination of the proposed acquisition to CFIUS pursuant to subsection (b) of this section, the Purchasers and Aixtron shall certify to CFIUS on a weekly basis that they are in compliance with this order and include a description of efforts to permanently abandon the proposed acquisition of Aixtron US and a timeline for projected completion of remaining actions.

(d) Any transaction or other device entered into or employed for the purpose of, or with the effect of, avoiding or circumventing this order is prohibited.

(e) The Attorney General is authorized to take any steps necessary to enforce this order.

Sec. 3. *Reservation.* I hereby reserve my authority to issue further orders with respect to the Purchasers, Aixtron, or Aixtron US as shall in my judgment be necessary to protect the national security.

Sec. 4. *Publication and Transmittal.* (a) This order shall be published in the *Federal Register.*

(b) I hereby direct the Secretary of the Treasury to transmit a copy of this order to the appropriate parties named in section 1 of this order.

THE WHITE HOUSE,
December 2, 2016.

[FR Doc. 2016–29494
Filed 12–6–16; 11:15 am]
Billing code 3295–F7–P

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